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NORTHERN DISTRICT OF CALIFORNIA
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ANGIOSCORE, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

YGR

ANGIOSCORE, INC.,

Plaintiff,

v.

TRIREME MEDICAL, INC., EITAN KONSTANTINO, and QUATTRO VASCULAR PTE LTD.,

Defendants.

Case No. CV12-03393

COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

FAXED

Plaintiff AngioScore, Inc. ("AngioScore") files this Complaint against defendants TriReme Medical, Inc. ("TriReme"), Eitan Konstantino ("Konstantino"), and Quattro Vascular Pte Ltd. ("Quattro"), and demanding a trial by jury, alleges as follows:

INTRODUCTION

1. This is an action for patent infringement. Specifically, AngioScore seeks remedies for TriReme, Konstantino, and Quattro's (collectively the "Defendants'") infringement of its United States Patent No. 7,691,119 ("the '119 patent") and United States Patent No. 7,931,663 ("the '663 patent"). True and correct copies of the '119 and '663 patents (collectively the "Asserted Patents") are attached hereto as **Exhibits A & B**, respectively.

PARTIES

2. AngioScore is a corporation organized and existing under the laws of the State of Delaware, having its corporate headquarters and principal place of business at 5055 Brandin Court, Fremont, California 94538, and does business in the Northern District of California.

3. On information and belief, TriReme: (i) is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters and principal place of business at 7060 Koll Center Parkway, Suite 300, Pleasanton, California 94566; (ii) may be served with process by serving its registered agent (Konstantino) at 7060 Koll Center Parkway, Suite 300, Pleasanton, California 94566; and (iii) does business in the Northern District of California.

4. On information and belief, Konstantino is a resident of Orinda, California and is the Chief Executive Officer of both TriReme and Quattro.

5. On information and belief, Konstantino is the principal decision maker with regard to what products will be manufactured and sold by TriReme and Quattro.

6. On information and belief, Quattro operates as a subsidiary of TriReme and has a place of business at 2 Shenton Way, # 18-01, SGX Center One, Singapore 068804.

7. On information and belief, Konstantino is a founder of both TriReme and Quattro.

JURISDICTION AND VENUE

8. This lawsuit is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. Accordingly, this Court has original subject matter jurisdiction pursuant to 28 U.S.C. §§1331 & 1338(a).

9. This Court also has personal jurisdiction over TriReme, Konstantino, and Quattro for at least the following reasons: (i) on information and belief, TriReme's corporate headquarters and principal place of business are located in the Northern District of California; (ii) TriReme, Konstantino, and Quattro have committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in this District and elsewhere in California and the United States; (iii) TriReme, Konstantino, and Quattro regularly do business or solicit business, engage in other persistent courses of conduct, and/or derive substantial revenue from products and/or services provided to individuals/entities in this District and in this State; and (iv) TriReme, Konstantino, and Quattro have purposefully established substantial, systematic, and continuous contacts with this District and expect or should reasonably expect to be sued here. This Court's exercise of jurisdiction over TriReme, Konstantino, and Quattro will therefore not offend traditional notions of fair play and substantial justice.

10. Venue is proper in this District pursuant to 28 U.S.C. §§1391(b)&(c), as well as 28 U.S.C. §1400(b), with respect to TriReme and Konstantino. Both TriReme and Konstantino do business and are residents of the State of California, both have committed acts of infringement in this State and in this District, a substantial part of the events or omissions giving rise to this Complaint occurred in this District, and TriReme is subject to and has previously subjected itself to personal jurisdiction in this District. TriReme's corporate headquarters are also located in this District. Venue is also proper in this District with respect to Quattro, pursuant to 28 U.S.C. §§1391(b)&(c). While Quattro is not a resident of the United States, it may be sued in any judicial district.

INTRADISTRICT ASSIGNMENT

11. This is an Intellectual Property Action to be assigned on a district-wide basis pursuant to Civil Local Rule 3-2(c).

BACKGROUND

The Asserted Patents

12. AngioScore is the owner by assignment of all rights, title, and interest in the Asserted Patents, including the right to bring this suit for injunctive relief and damages.

13. The '119 patent, entitled "Balloon Catheter With Non-Deployable Stent," was duly and legally issued by the United States Patent and Trademark Office on April 6, 2010, and claims "[a]n angioplasty balloon catheter."

14. The '663 patent, also entitled "Balloon Catheter With Non-Deployable Stent," was duly and legally issued by the United States Patent and Trademark Office on April 26, 2011, and claims "[a] method for performing angioplasty" using a balloon catheter and "[a]n angioplasty catheter" having a balloon.

History

15. Konstantino was employed by AngioScore for several years, and left the employ of AngioScore in 2006.

16. On information and belief, Konstantino is a founder of both TriReme and Quattro.

17. TriReme and Quattro compete, or seek to compete, with AngioScore in the United States and around the world in the angioplasty market. TriReme, Konstantino, and Quattro offer an angioplasty balloon catheter sold under the name "Chocolate."

18. TriReme, Konstantino, and Quattro have infringed, and continue to infringe, the Asserted Patents by making, selling, offering to sell, importing, using, and/or inducing others to use balloon angioplasty products, including balloon angioplasty catheters sold under the name "Chocolate."

19. On information and belief, TriReme and Konstantino design their angioplasty products, including the Chocolate balloon angioplasty catheters, in the United States, and particularly in the Northern District of California.

20. Konstantino is a named inventor on United States Patent Application Serial No. 13/044,425, which has been assigned Publication No. 2012/0059401, and which is directed to the Chocolate balloon angioplasty catheters.

21. In a December, 2011 press release, TriReme announced that it had "received 510(k) clearance from the United States Food and Drug Administration to market its Chocolate PTA balloon catheter ('Chocolate') for the treatment of occluded peripheral arteries." As stated in the press release, "PTA" means "percutaneous transluminal angioplasty."

22. The 510(k) clearance letters from the FDA, dated December 14, 2011 and March 15, 2012, state that the Chocolate device is cleared for use in the "balloon dilation of lesions in the peripheral vasculature."

23. Konstantino has been aware of the Asserted Patents since his employment at AngioScore, which ended in 2006. AngioScore's Angiosculpt balloon angioplasty products and their packaging are also marked with the '119 and '663 patent numbers.

24. TriReme has sold and continues to sell the infringing Chocolate balloon angioplasty catheters in the United States. IDEV Technologies, Inc. is a distributor through which TriReme sells Chocolate balloon angioplasty catheters in the United States.

25. TriReme imports Chocolate balloon angioplasty catheters, which are made by Quattro in Singapore, into the United States.

26. TriReme, Konstantino, and Quattro also indirectly infringe the Asserted Patents. Each of them knowingly induces distributors, consumers, and end-users to directly infringe the Asserted Patents by selling or using the Chocolate angioplasty balloon products. The Chocolate angioplasty balloon products have been used in the United States by Dr. Jihad Mustapha, as set forth in a TriReme press release dated December 21, 2011. TriReme's marketing, sales, and customer support materials instruct customers to use the infringing Chocolate balloon angioplasty products to treat occlusions in blood vessels.

27. The Chocolate angioplasty balloon products do not have a substantial non-infringing use.

28. On information and belief, TriReme and Quattro also have had notice of the '119 and '663 patents at all relevant times discussed herein through, at least, the imputed knowledge of Konstantino and AngioScore's marking of its Angiosculpt balloon angioplasty products with the '119 and '663 patent numbers.

Infringement by the Defendants Harms AngioScore

29. AngioScore is harmed by the infringement of the Asserted Patents by TriReme, Konstantino, and Quattro in a way that cannot be remedied by monetary damages alone. The Chocolate balloon angioplasty products compete directly with AngioScore's Angiosculpt balloon angioplasty devices, which are AngioScore's principal product.

30. On information and belief, infringement by TriReme, Konstantino, and Quattro has caused AngioScore to suffer irreparable harm due to, among other things, lost business opportunities, lost market share, and price erosion. Even if TriReme, Konstantino, and Quattro were to subsequently pay past due royalties, lost profits, or other damages, there is no reason to believe that TriReme, Konstantino, or Quattro would stop infringing, and they would still enjoy the market share they have developed while infringing upon the Asserted Patents. Due to the difficulty in predicting whether, if at all, AngioScore can recover this market share, AngioScore's harm cannot be compensated by the payment of monetary damages alone.

FIRST CAUSE OF ACTION

(Patent Infringement – 35 U.S.C. § 271, *et seq.*)

(United States Patent No. 7,691,119)

31. AngioScore incorporates by reference the preceding averments set forth in paragraphs 1-30.

32. Each of TriReme, Konstantino, and Quattro have infringed and continue to infringe, have contributed and continue to contribute to acts of infringement, and/or have actively and knowingly induced and continue to actively and knowingly induce the infringement of the '119 patent by making, using, offering for sale, and selling in the United States, by importing into the United States without authority, and/or by causing others to make, use, offer for sale, and sell in the United States, and import into the United States without authority, the Chocolate balloon angioplasty products.

33. The infringement, contributory infringement, and/or inducement of infringement by TriReme, Konstantino, and Quattro is literal infringement or, in the alternative, infringement under the doctrine of equivalents.

34. The infringing activities of TriReme, Konstantino, and Quattro have caused and will continue to cause AngioScore irreparable harm, for which it has no adequate remedy at law, unless the infringing activities of TriReme, Konstantino, and Quattro are enjoined by this Court in accordance with 35 U.S.C. §283.

35. AngioScore has been and continues to be damaged by the infringement by TriReme, Konstantino, and Quattro of the '119 patent in an amount to be determined at trial.

36. On information and belief, the infringement of the '119 patent by TriReme, Konstantino, and Quattro has been willful and deliberate, entitling AngioScore to enhanced damages and attorneys' fees.

SECOND CAUSE OF ACTION

(Patent Infringement – 35 U.S.C. § 271, *et seq.*)

(United States Patent No. 7,931,663)

37. AngioScore incorporates by reference the preceding averments set forth in paragraphs 1-30.

38. Each of TriReme, Konstantino, and Quattro have infringed and continue to infringe, have contributed and continue to contribute to acts of infringement, and/or have actively and knowingly induced and continue to actively and knowingly induce the infringement of the '663 patent by making, using, offering for sale, and selling in the United States, by importing into the United States without authority, and/or by causing others to make, use, offer for sale, and sell in the United States, and import into the United States without authority, the Chocolate balloon angioplasty products.

39. The infringement, contributory infringement, and/or inducement of infringement by TriReme, Konstantino, and Quattro is literal infringement or, in the alternative, infringement under the doctrine of equivalents.

40. The infringing activities of TriReme, Konstantino, and Quattro have caused and will continue to cause AngioScore irreparable harm, for which it has no adequate remedy at law, unless the infringing activities of TriReme, Konstantino, and Quattro are enjoined by this Court in accordance with 35 U.S.C. §283.

41. AngioScore has been and continues to be damaged by the infringement by TriReme, Konstantino, and Quattro of the '663 patent in an amount to be determined at trial.

42. On information and belief, the infringement of the '663 patent by TriReme, Konstantino, and Quattro has been willful and deliberate, entitling AngioScore to enhanced damages and attorneys' fees.

REQUEST FOR RELIEF

WHEREFORE, AngioScore respectfully requests that:

(a) Judgment be entered that each of TriReme, Konstantino, and Quattro has infringed one or more claims of each of the Asserted Patents;

(b) Judgment be entered permanently enjoining TriReme, Konstantino, and Quattro and their directors, officers, agents, servants, and employees, and those acting in privity or in concert with them, and their subsidiaries, divisions, successors, and assigns, and Konstantino from further acts of infringement, contributory infringement, or inducement of infringement of the Asserted Patents;

(c) Judgment be entered awarding AngioScore all damages adequate to compensate it for infringement of the Asserted Patents, including all pre-judgment and post-judgment interest at the maximum rate permitted by law and enhanced damages;

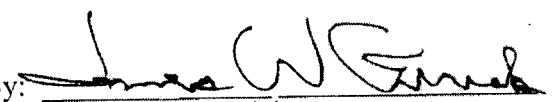
(d) Judgment be entered that this is an exceptional case and awarding AngioScore attorneys' fees and costs under 35 U.S.C. §285; and

(e) Judgment be entered awarding AngioScore such other and further relief as this Court may deem just and proper.

Dated: June 29, 2012

Respectfully submitted,

DICKSTEIN SHAPIRO LLP

By: 

James W. Geriak
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ANGIOSCORE, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ANGIOSCORE, INC., Plaintiff, v. TRIREME MEDICAL, INC., EITAN KONSTANTINO, and QUATTRO VASCULAR PTE LTD., Defendants.	Case No. **DEMAND FOR JURY TRIAL**

TO EACH PARTY AND TO THE COUNSEL OF RECORD FOR EACH PARTY:

Plaintiff AngioScore, Inc. hereby demands a jury trial in the above-entitled action pursuant to Rule 38(b) of the Federal Rules of Civil Procedure.

Dated: June 29, 2012

Respectfully submitted,

DICKSTEIN SHAPIRO LLP

By: _____

James W. Geriak
Attorneys for Plaintiff
ANGIOSCORE, INC.

EXHIBIT A

US007691119B2

(12) **United States Patent**
Farnan

(10) **Patent No.: US 7,691,119 B2**
(45) **Date of Patent: Apr. 6, 2010**

(54) **BALLOON CATHETER WITH NON-DEPLOYABLE STENT**

(75) Inventor: **Robert C. Farnan**, Davie, FL (US)

(73) Assignee: **AngioScore, Inc.**, Fremont, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 759 days.

(21) Appl. No.: **10/399,589**

(22) PCT Filed: **Nov. 6, 2002**

(86) PCT No.: **PCT/US02/35547**

§ 371 (c)(1),
(2), (4) Date: **Sep. 2, 2003**

(87) PCT Pub. No.: **WO03/041760**

PCT Pub. Date: **May 22, 2003**

(65) **Prior Publication Data**

US 2005/0049677 A1 Mar. 3, 2005

(51) **Int. Cl.**
A61B 17/22 (2006.01)
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **606/194**; 606/191; 606/159

(58) **Field of Classification Search** 606/191, 606/194, 159; 623/1.23; 604/103.07, 103.08
See application file for complete search history.

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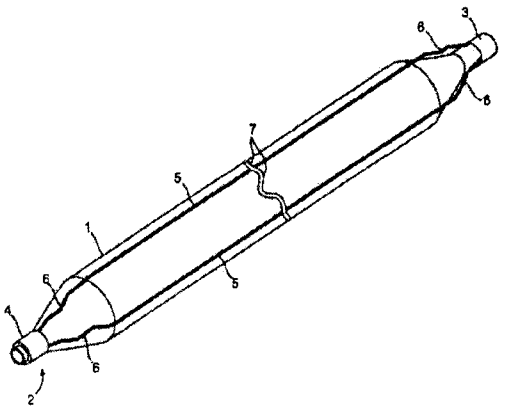
Primary Examiner—Julian W Woo
Assistant Examiner—Melissa Ryckman
(74) *Attorney, Agent, or Firm*—Townsend and Townsend and Crew LLP

(57) **ABSTRACT**

An angioplasty balloon including a non-deployable stent to prevent or reduce the potential for slippage of the inflated balloon with respect to the vessel wall being treated. The balloon includes a non-deployable stent that is adapted to be secured to the balloon or angioplasty balloon catheter. The stent has a proximal end, a distal end, and at least three radially-spaced struts, each strut connecting the proximal end to the distal end and having one or more bends that allow expansion of the strut to accommodate the inflation of the balloon. The stent is made of a material so that the stent collapses upon deflation or the balloon.

9 Claims, 11 Drawing Sheets



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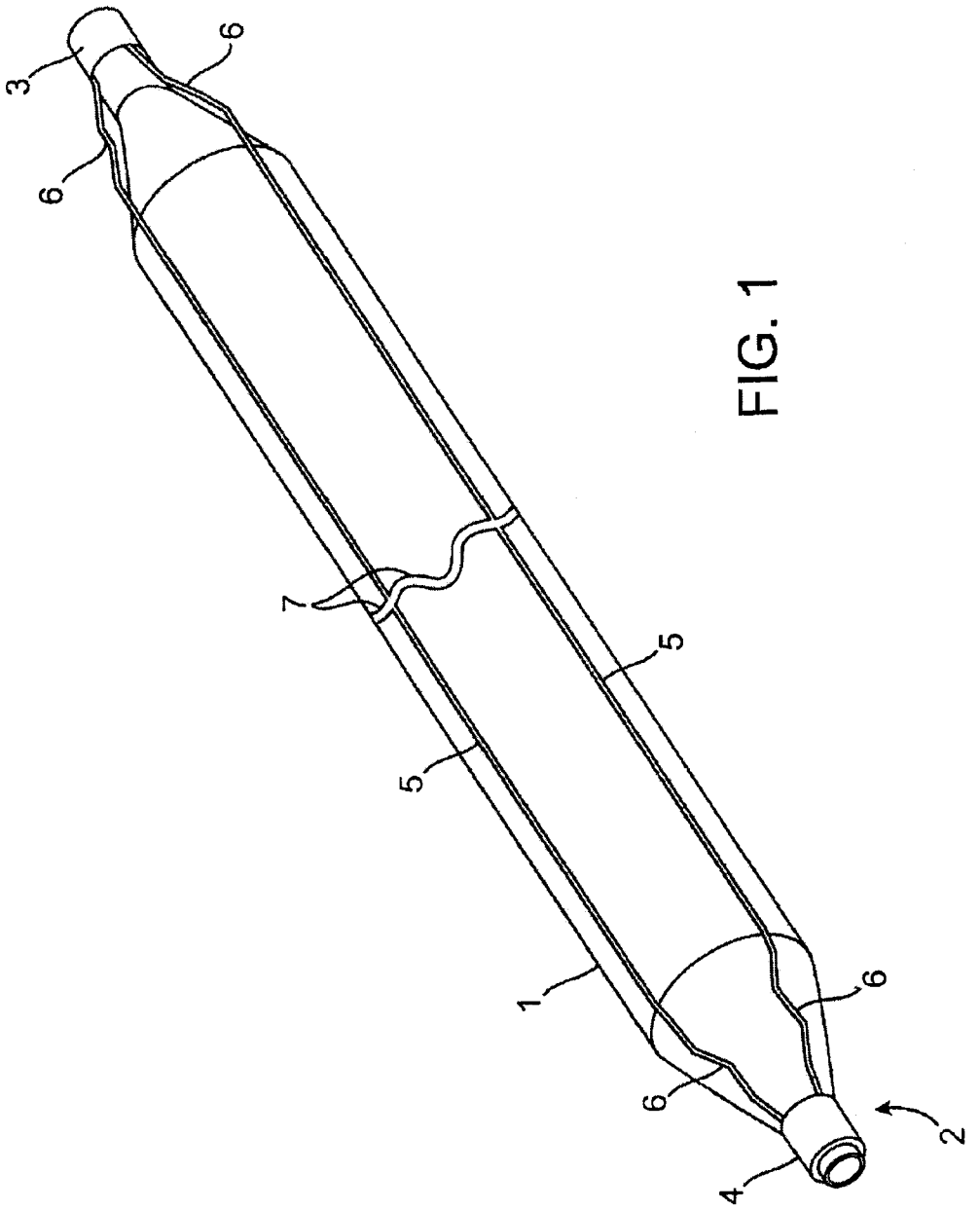

FIG. 1

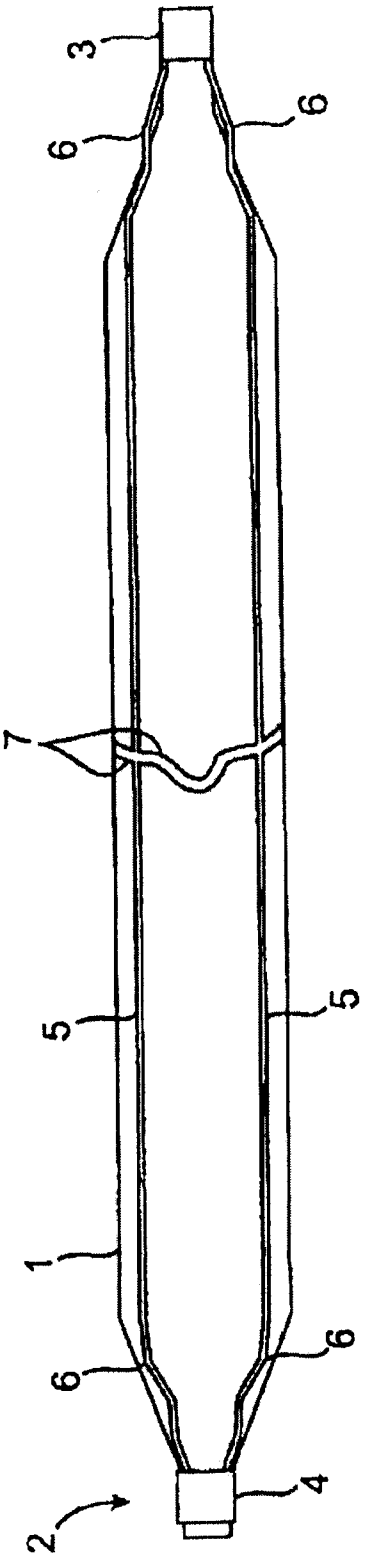

FIG. 2

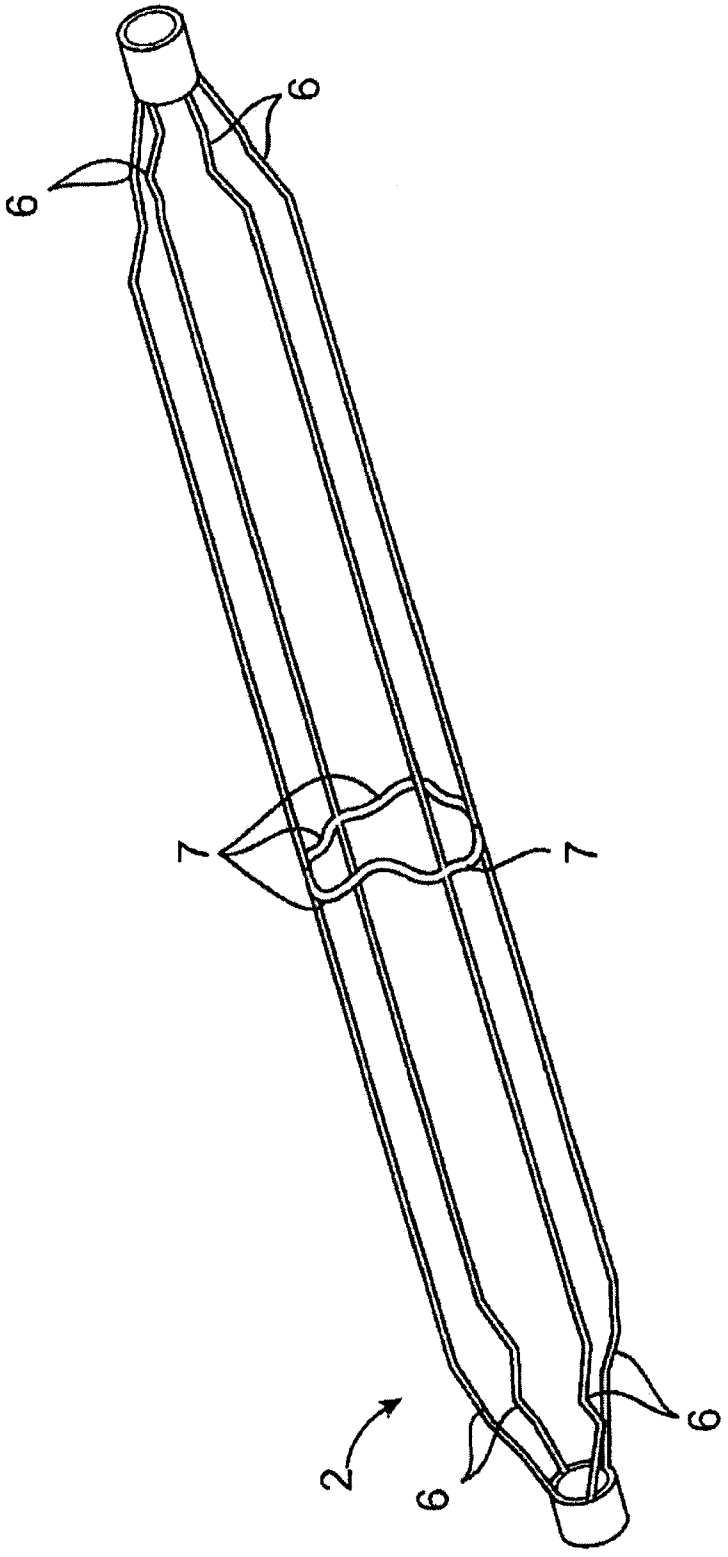

FIG. 3

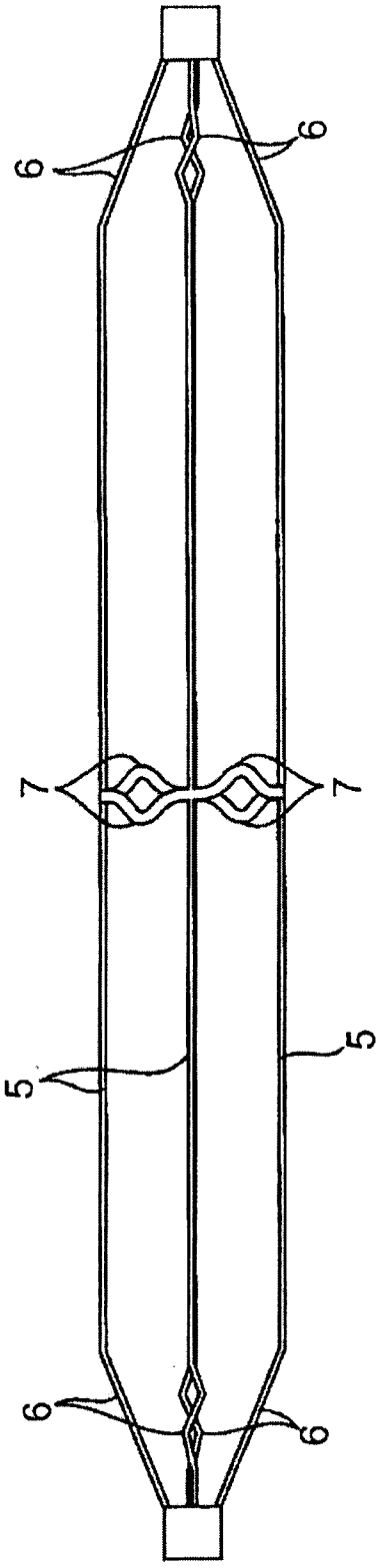

FIG. 4

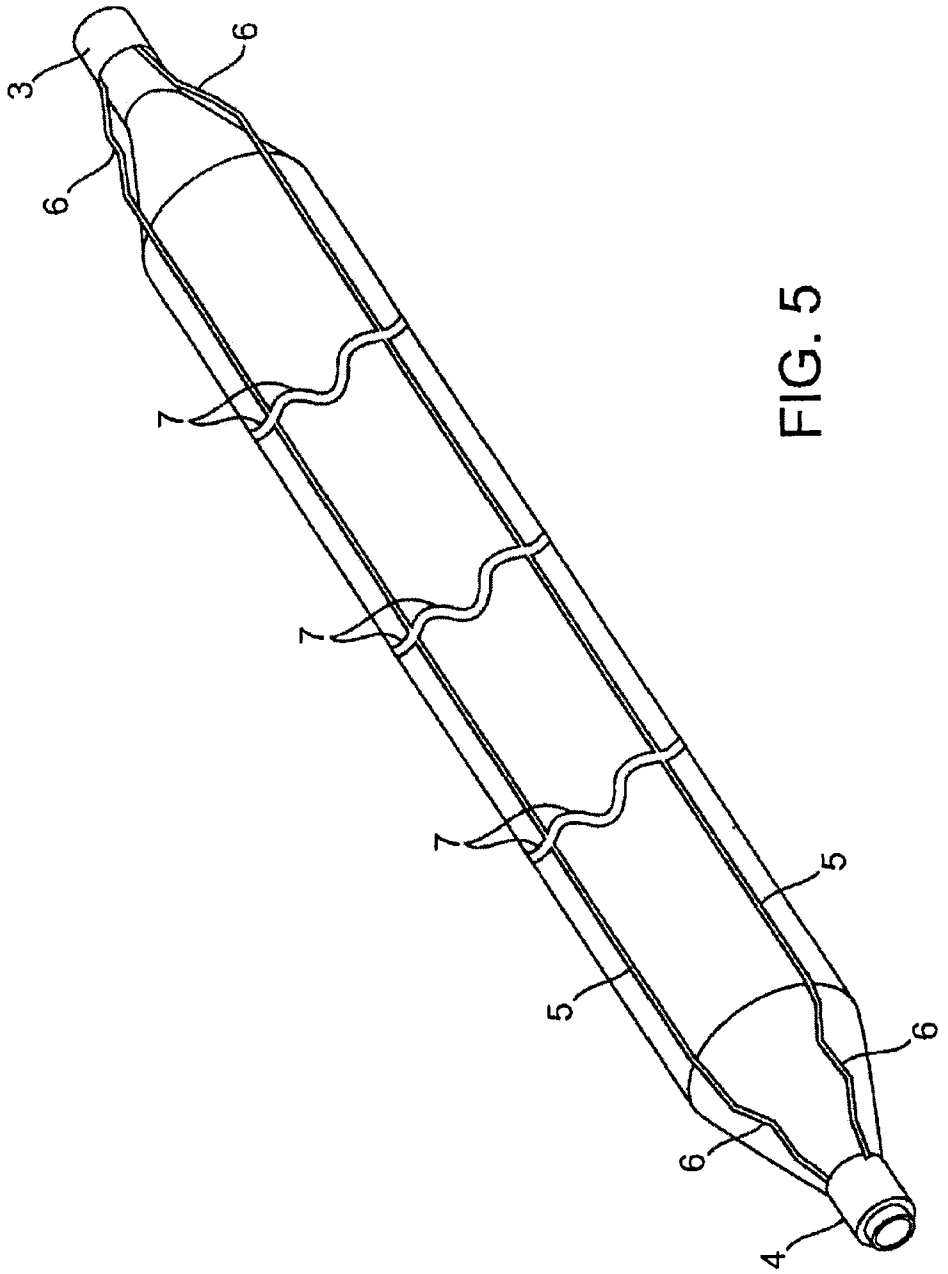

FIG. 5

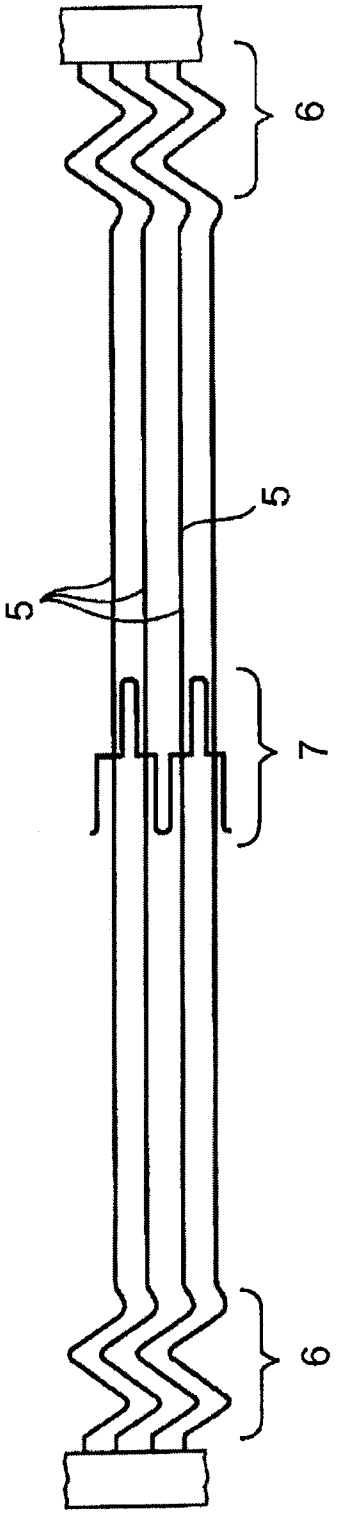

FIG. 6

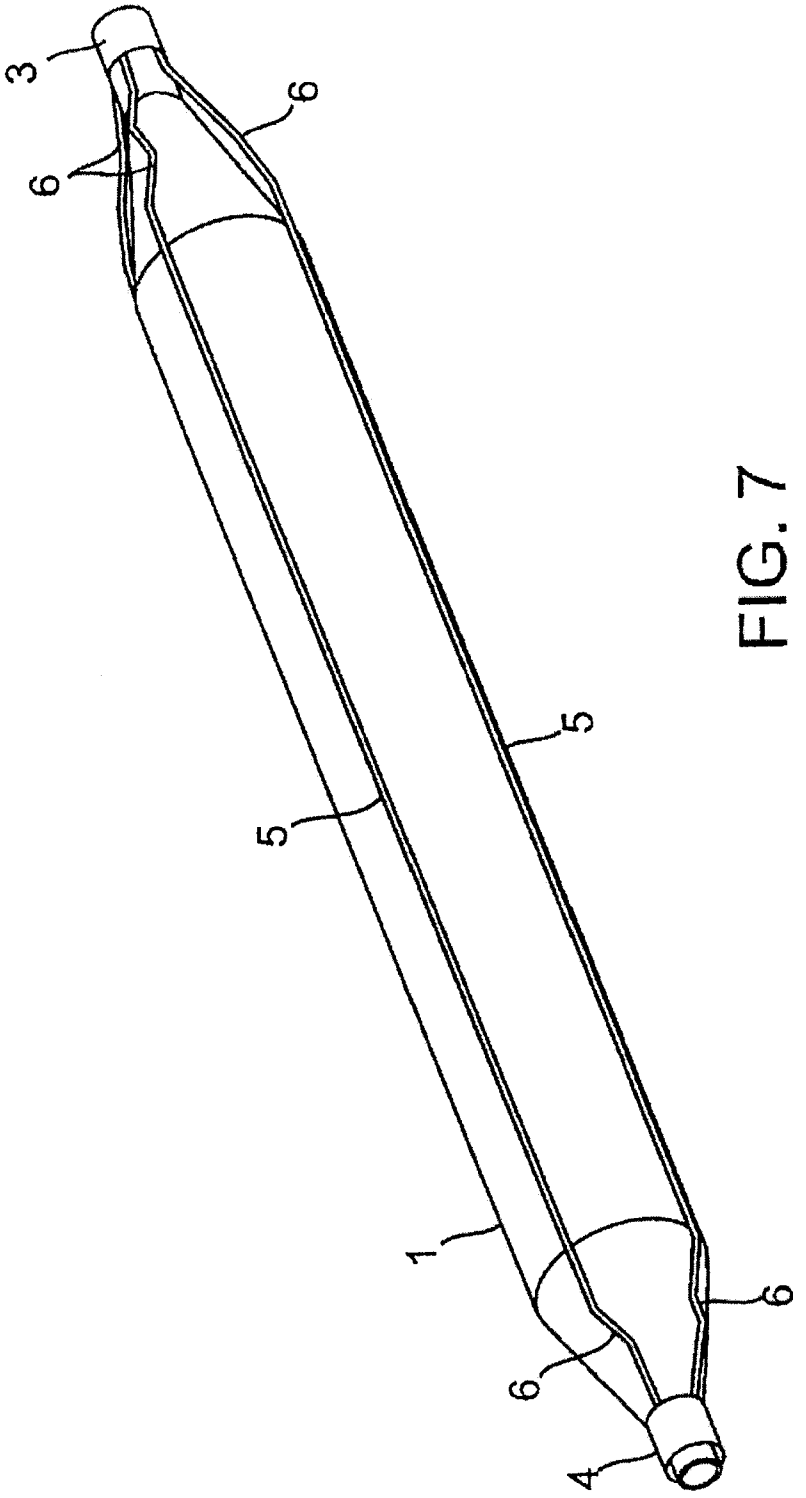

FIG. 7

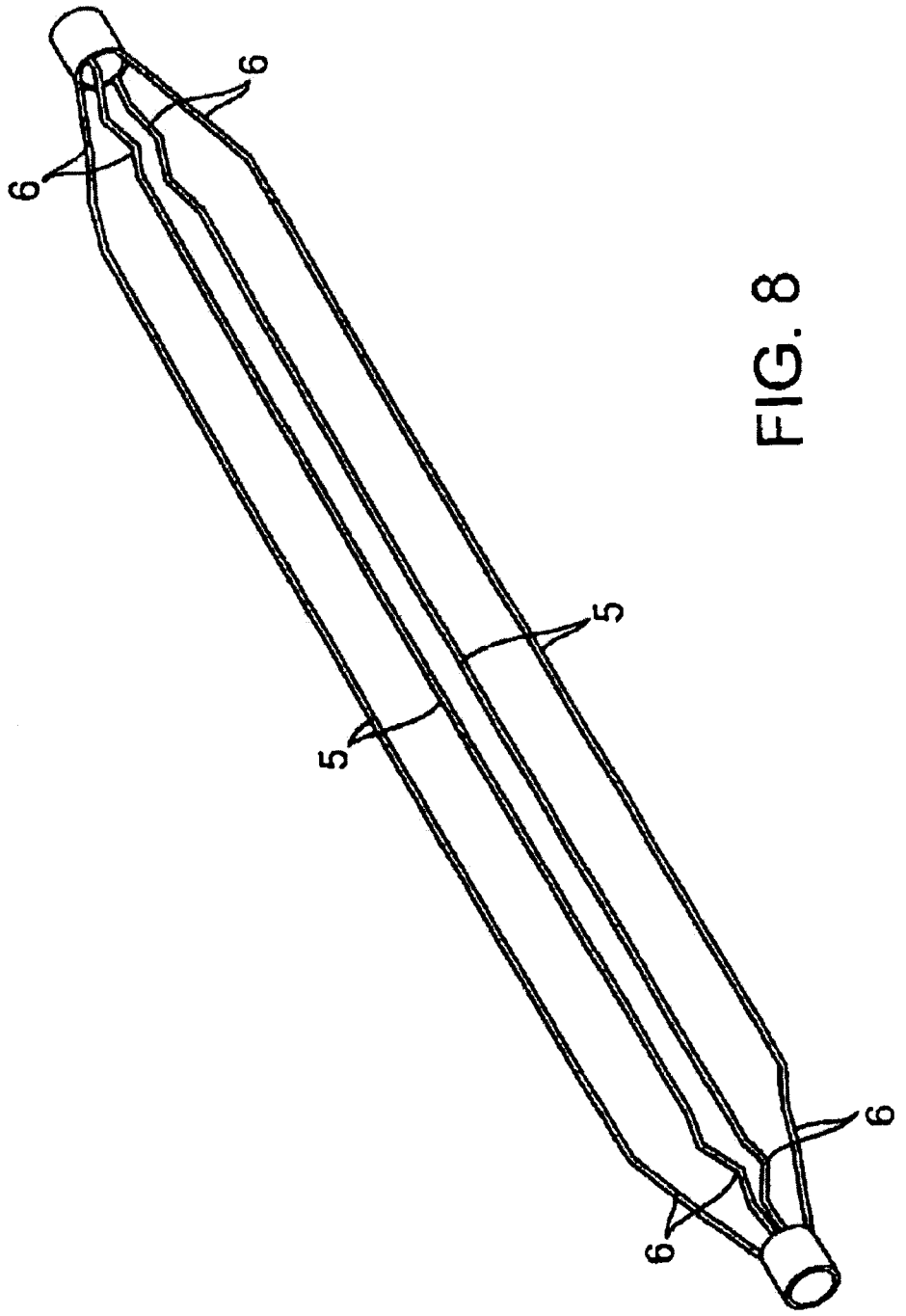

FIG. 8

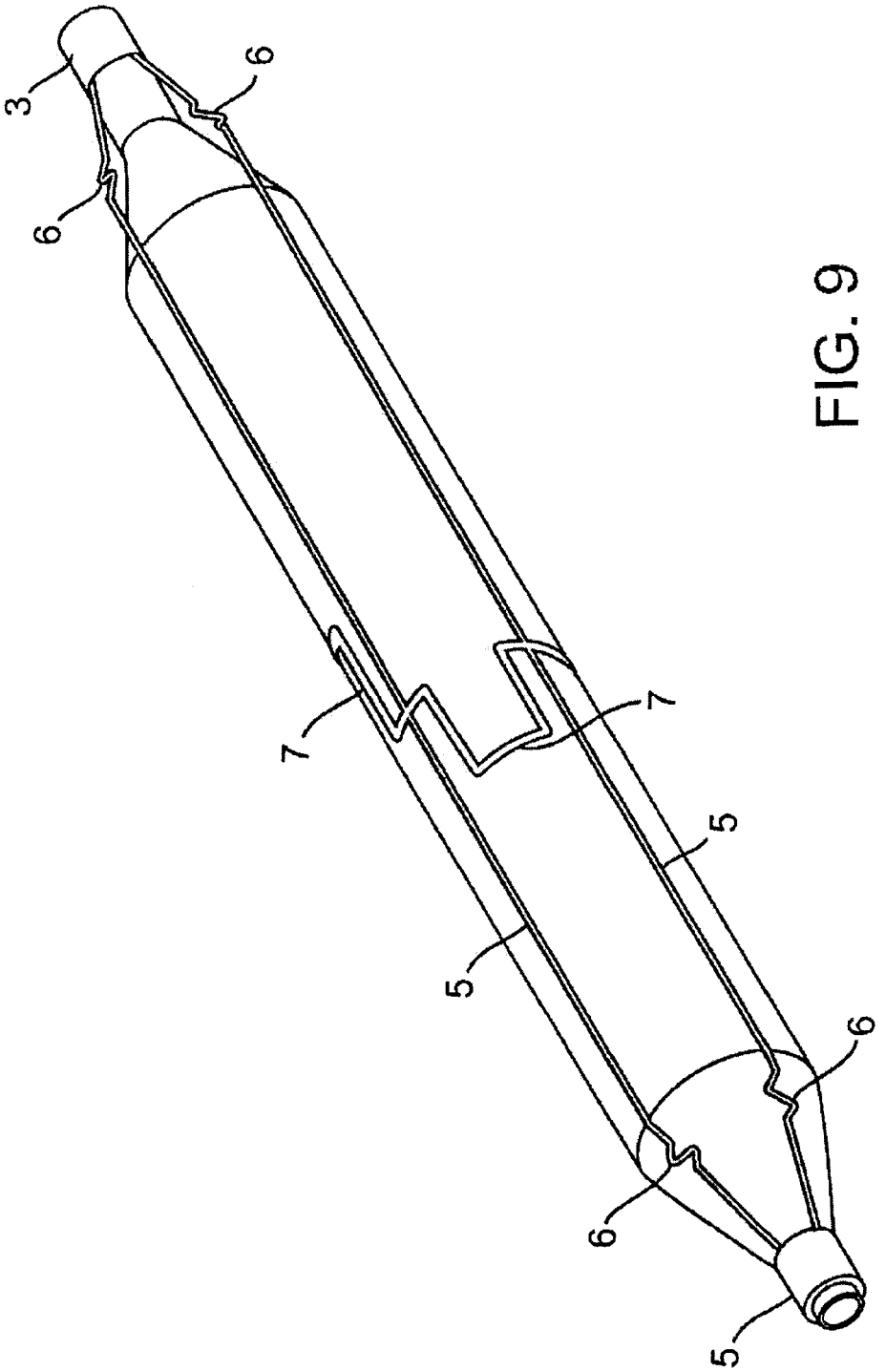

FIG. 9

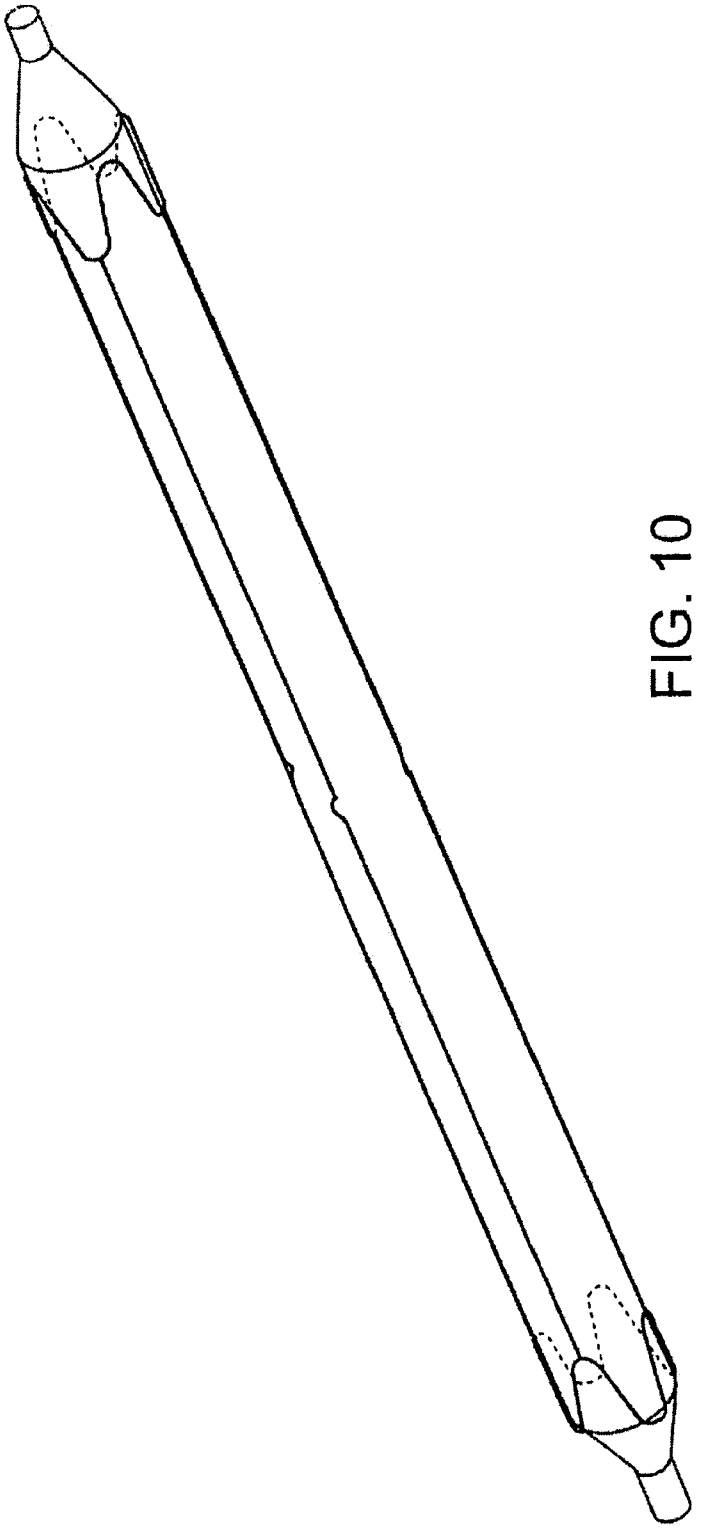

FIG. 10

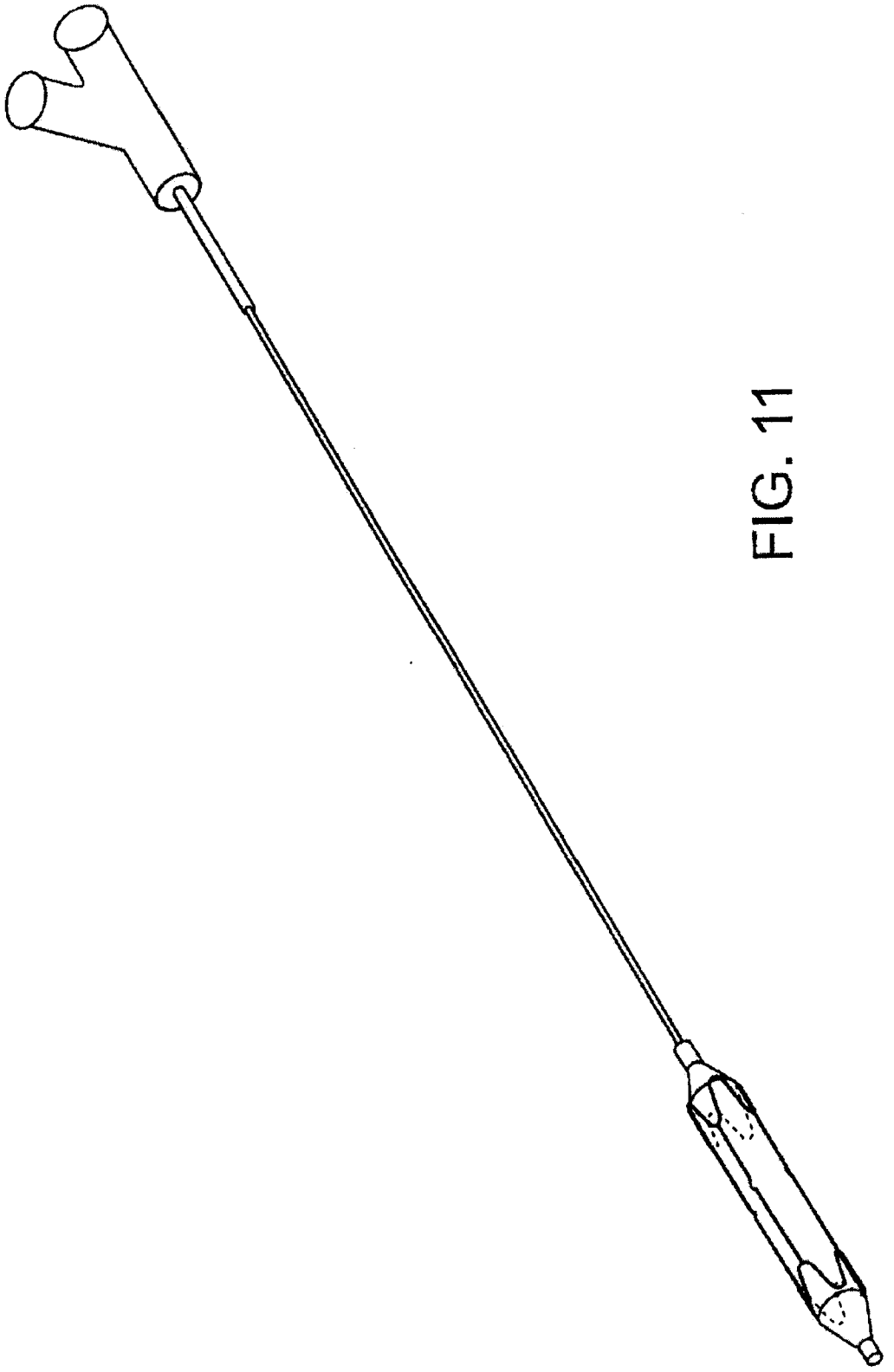

FIG. 11

BALLOON CATHETER WITH NON-DEPLOYABLE STENT

BACKGROUND OF THE INVENTION

When a balloon used for percutaneous transluminal angioplasty (PTA) or percutaneous transluminal coronary angioplasty (PTCA) is inflated and forced into contact with the plaque, the balloon can have a tendency to move or slip longitudinally in relation to the lesion or the vessel wall being treated.

Cutting balloons (atherotomy) have recently shown clinical efficacy in preventing the reoccurrence of some types of restenosis (specifically calcified lesions and in-stent restenosis). The cutting balloon is a coronary dilatation catheter with 3 to 4 atherotomes (microsurgical blades) bonded longitudinally on the balloon surface. As the cutting balloon is inflated, the atherotomes move radially and open the occluded artery by incising and compressing the arterial plaque in a controlled manner. An additional advantage of the cutting balloon is that it maintains its position during inflation by using the metal blades on the external surface of the balloon to penetrate into the tissue and prevent the balloon from moving.

Accordingly, it is the principal objective of the present invention to provide a PTA or PTCA balloon that, like a cutting balloon, has a reduced potential of slippage when inflated in a vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an inflated angioplasty balloon incorporating a non-deployable stent according to the present invention.

FIG. **2** is a plan view of the inflated angioplasty balloon and non-deployable stent of FIG. **1**.

FIG. **3** is a perspective view of the non-deployable stent in its expanded condition, as shown in FIG. **1**, with the angioplasty balloon removed so as to more clearly show the stent.

FIG. **4** is a plan view of the non-deployable stent of FIG. **3**.

FIG. **5** is a perspective view of an alternate embodiment of the non-deployable stent associated with an angioplasty balloon that has a longer working length than the angioplasty balloon shown in FIGS. **1** and **2**.

FIG. **6** is an engineering drawing showing, in plan view, the layout of a non-deployable stent adapted to be used with an angioplasty balloon of 20 mm in length. (All dimensions shown in the drawing are in inches.)

FIG. **7** is a perspective view of an inflated angioplasty balloon incorporating an alternative embodiment of a non-deployable stent which does not include any connecting elements between the struts intermediate the ends of the balloon.

FIG. **8** is a perspective view of the non-deployable stent shown in FIG. **7**, with the angioplasty balloon removed so as to more clearly show the stent.

FIGS. **9** and **10** are perspective views similar to FIGS. **1**, **5**, and **7** showing a further embodiment of the invention.

FIG. **11** is a perspective view of a further embodiment of the present invention showing the balloon and non-deployable stent in conjunction with a catheter.

DESCRIPTION

The non-deployable stent of the present invention may be used in conjunction with a conventional balloon catheter. A PTA or PTCA catheter (dilatation catheter) may be a coaxial catheter with inner and outer members comprising a guide wire lumen and a balloon inflation lumen, respectively. Each

member can have up to 3 layers and can be reinforced with braids. The proximal end of the catheter has a luer hub for connecting an inflation means, and a strain relief tube extends distally a short distance from the luer hub. The distal ends of the outer and inner members may include a taper. The catheter shaft is built using conventional materials and processes. A catheter having multi-durometer tubing with variable stiffness technology is also a possibility. The catheter should be compatible with a 6 F guide catheter. Optionally, the catheter may be a multi-lumen design.

The balloon **1** may be made of either nylon or nylon copolymer (compliant, non-puncture) or PET (high pressure, non-compliant) with a urethane coating to provide tackiness. The balloon may be a multi-layered balloon with a non-compliant inner layer to a most compliant outer layer. For example, a inner most layer of PET, which provides a higher pressure balloon, surrounded by an outer layer of nylon, which provides a more puncture-resistant surface. The balloon may be from 1.5-12 mm in diameter (1.5-4 mm for coronary and 4-12 mm for peripheral vessels) and 15-60 mm in length (15-40 mm for coronary and up to 60 mm for peripheral vessels). The balloon inflation pressure will be from 8-20 atmospheres, depending on the wall thickness of the balloon. When inflated, the balloon ends or necks are cone-shaped.

In keeping with the invention, the balloon is provided with a Nitinol (NiTi) structure, generally designated **2**, that incorporates bends for both radial and longitudinal expansion of the Nitinol structure **2** in response to longitudinal and radial expansion of the balloon during inflation, so that the Nitinol structure **2** maintains the balloon in its intended position during inflation. This Nitinol structure **2** can be described as a non-deployable or temporary stent that provides for both controlled cracking of vessel occlusion and gripping of vessel wall during an angioplasty procedure. The Nitonol structure **2** comprises a laser cut hypo tube that expands upon inflation of the balloon, but collapses upon deflation of the balloon because of the super-elastic properties of the Nitinol material, rather than remain expanded in the deployed condition, as would stents in general.

The Nitinol structure or non-deployable stent **2** has a proximal end **3**, a distal end **4**, and, therebetween, anywhere from 3-12 struts or wires **5** (depending on balloon size—but most likely 3-4 struts) with a pattern of radial and longitudinal bends. The use of laser cutting in connection with stent manufacture is well known (See, e.g., Meridan et al. U.S. Pat. No. 5,994,667), as is the use of the super-elastic nickel—titanium alloy Nitinol (see e.g., Huang et al. U.S. Pat. No. 6,312,459).

As seen in FIGS. **1-4**, each end of the linear, longitudinally aligned four struts **5** has a sinusoidal bend **6** that allows the laser cut hypo tube to expand longitudinally when the balloon **1** is inflated. The linear length of the sinusoidal bends **6** is sized to accommodate the longitudinal expansion of the balloon **1** due to inflation. The strut or wire **5** cross sectional shape can be round, triangular or rectangular. Preferred diameter of the struts **5** ranges from 0.003 to 0.010 inch.

At the longitudinal center of the hypo tube, a U-shaped circumferential connector **7** joins each strut **5** to its adjacent strut. As best seen in FIGS. **3** and **4**, the U-shaped connectors **7** are on opposing sides of the central radial axis. The distal end **4** of the hypo tube is adhered to the distal neck of the balloon or the distal end of the catheter shaft, and the proximal end **3** of the hypo tube is either attached to the proximal neck of the balloon or to the proximal end of the catheter shaft. The struts **5** may be attached to the working region of the balloon **1** to assist the hypo tube in staying with the balloon as it

inflates and deflates, and an adhesive, such as a cyanoacrylate adhesive, may be used to tack the struts down onto balloon at various points.

Catheter shafts to which the balloon and laser cut hypo tube are attached can have diameters ranging from 2.5 F to 8 F, and the distal end may be tapered and slightly less in diameter than the proximal end.

In FIG. **6**, the dimensions of the laser cut hypo tube are for use with a 3 mm (0.118 in) diameter by 20 mm length balloon. The circumference of a 3 mm balloon is nD=3.14(3 mm)=9.42 mm or 0.37 in. As can be readily appreciated, the total length of all U-shaped connectors **7** (up and back) must be greater than the circumference of the inflated balloon **1**. The length of each U-shaped connector **7** (up and back), may be calculated using the following equation:

$$\frac{\Pi d}{n},$$

where d is the diameter of the inflated balloon and n is the number of struts. The total length of the U-shaped bends (up and back) must exceed this length.

The resulting number is divided by 2 to get the length which each up-and-back side of the U-shaped connector should exceed. For example: for a 3 mm balloon compatible, laser-cut hypo tube with four struts, the length of each U-shaped connector (up and back) is 0.37 inch divided by 4=0.0925 in. Further divide by 2 and to get 0.04625 in. This is the length that each side of the U-shaped connector must exceed.

There is also one or more sets of U-shaped connectors **7** in between the sinusoidal bends **6**. The set includes one U-shaped connector for each strut (3 struts—a set of 3 U-shaped connectors; 4 struts—a set of 4 U-shaped connector; and so on). The number of U-shaped connector sets depends on the length of the balloon and thus, the length of the laser cut hypo tube. For a 20 mm length balloon, there is one set of U-shaped connectors spaced 10 mm from the end (at the halfway point along length of balloon). For a 40 mm length balloon, there are three sets of U-shaped connectors spaced in 10 mm increments (the first set is spaced 10 mm from one end; the second set is spaced 10 mm from first set; and the third set is spaced 10 mm from each the second set and the other end). The equation for number of sets of U-shaped connectors.

$$\frac{L}{10} - 1,$$

where L=length of balloon in mm. Other embodiments, such as those shown in FIGS. **7** and **8**, have linear, longitudinally aligned struts **5** with bends **6** at each end which do not incorporate the intermediate U-shaped connectors.

What is claimed:

1. An angioplasty balloon catheter comprising:

a catheter shaft carrying an inflatable/deflatable balloon having a proximal end and a distal end; and

a non-deployable radially expansible stent comprising a hypo tube disposed over the balloon and comprising a proximal end; a distal end; and at least three longitudinally aligned, radially-spaced struts, wherein each strut extends from the proximal end to the distal end and prior to radial expansion has one or more bends that allow longitudinal expansion of the strut to accommodate radial expansion of the stent upon inflation of the balloon; wherein the distal end of the hypo tube is attached to the distal end of the catheter shaft and the proximal end of the tube is attached to the proximal end of the catheter shaft and the stent is made of a material having a memory so that the stent radially collapses and the struts longitudinally shorten upon deflation of the balloon.

2. The angioplasty balloon of claim **1** wherein the stent is made of an alloy of nickel and titanium.

3. The angioplasty balloon of claim **1** wherein the struts of the stent have a diameter of from 0.003" to 0.010".

4. The angioplasty balloon of claim **1** wherein the bends in the struts of the stent are sinusoidal.

5. The angioplasty balloon of claim **1** wherein the hypo tube is laser cut.

6. The angioplasty balloon of claim **1** wherein the stent is secured to the balloon by an adhesive.

7. The angioplasty balloon of claim **6** wherein the adhesive is a cyanoacrylate.

8. The angioplasty balloon of claim **1** wherein the struts of the stent are connected to each other intermediate the proximal end and distal end by connectors that include a bend which allows longitudinal expansion of the connectors to accommodate radial expansion of the balloon.

9. The stent of claim **8** wherein the connectors in the struts comprise sinusoidal bends.

* * * * *

EXHIBIT B

US007931663B2

(12) **United States Patent**
Farnan et al.

(10) **Patent No.: US 7,931,663 B2**
(45) **Date of Patent: Apr. 26, 2011**

(54) **BALLOON CATHETER WITH NON-DEPLOYABLE STENT**

(75) Inventors: **Robert C. Farnan**, Davie, FL (US); **Dirk Voland Hoyns**, Conyers, GA (US); **Anand Ram**, Lilburn, GA (US)

(73) Assignee: **AngioScore, Inc.**, Fremont, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1304 days.

(21) Appl. No.: **11/292,426**

(22) Filed: **Dec. 1, 2005**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 10/651,557, filed on Aug. 29, 2003, now abandoned, which is a continuation-in-part of application No. 10/399,589, filed as application No. PCT/US02/35547 on Nov. 6, 2002, now Pat. No. 7,691,119.

(60) Provisional application No. 60/344,982, filed on Nov. 9, 2001.

(51) **Int. Cl.**
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **606/194**; 606/159

(58) **Field of Classification Search** 623/1.11, 623/1.17; 606/191–195, 159; 604/96.01, 604/97.01, 103, 103.05, 103.09, 104, 509

See application file for complete search history.

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Assistant Examiner — Erin Colello

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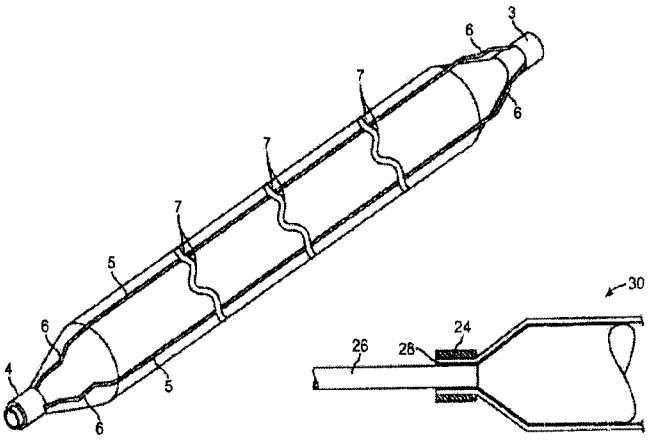
(57) **ABSTRACT**

An angioplasty balloon including a non-deployable stent to prevent or reduce the potential for slippage of the inflated balloon with respect to the vessel wall being treated. The balloon includes a non-deployable stent that is adapted to be secured to the balloon or angioplasty balloon catheter. The stent has a proximal end, a distal end, and at least one extension section, at least one set of serpentine rings and at least one set of elongation links that allow expansion of the strut to accommodate the inflation of the balloon. The stent is made of a material so that the stent collapses upon deflation of the balloon.

12 Claims, 13 Drawing Sheets



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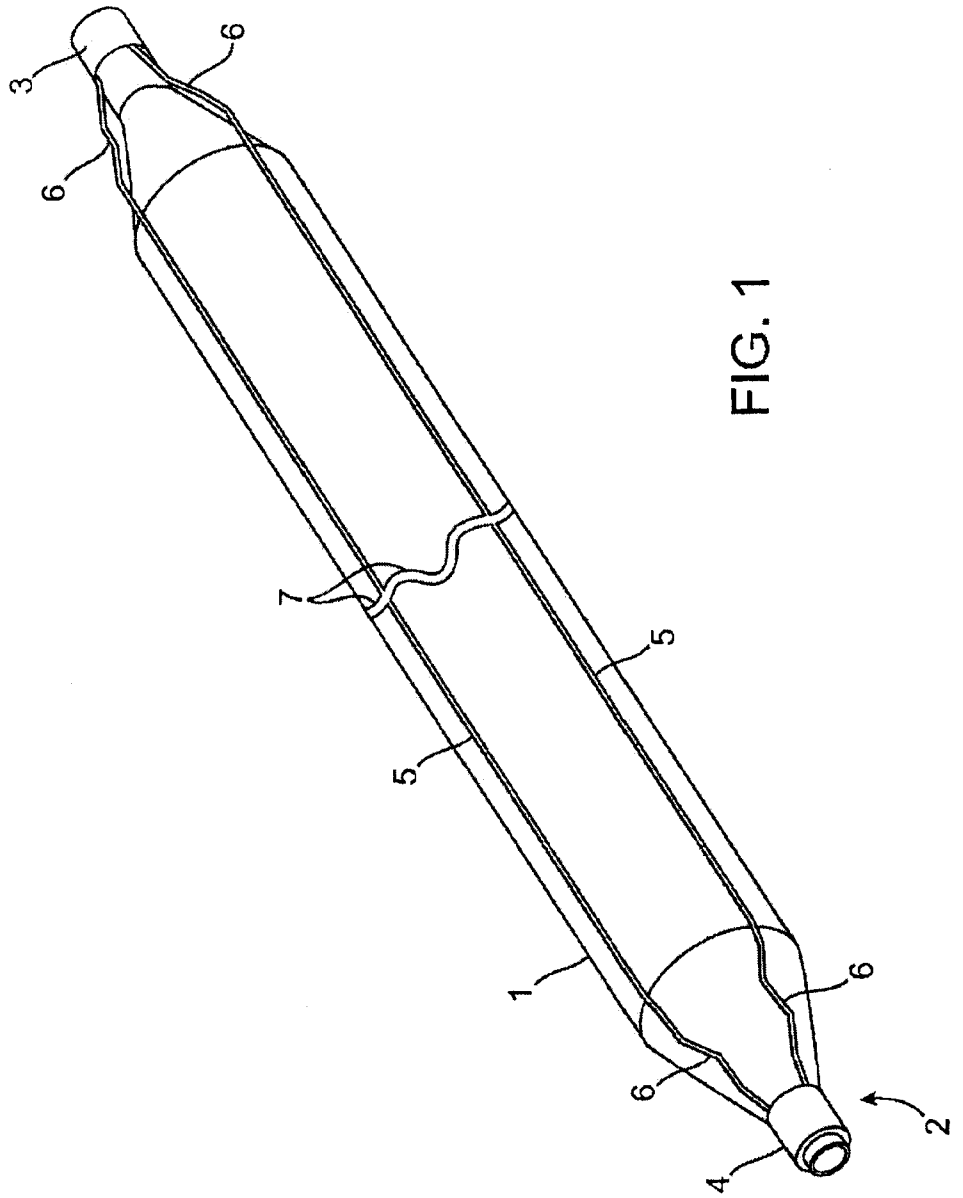

FIG. 1

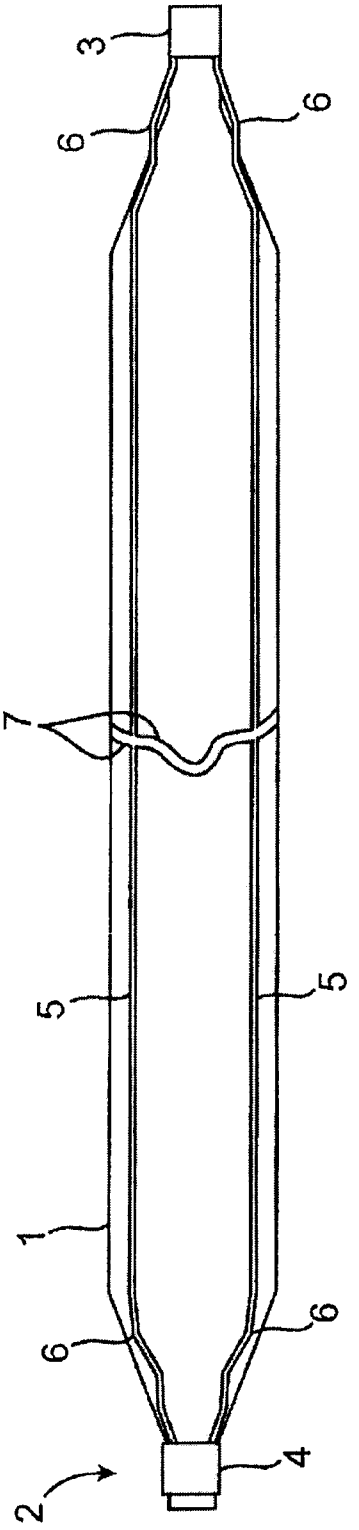

FIG. 2

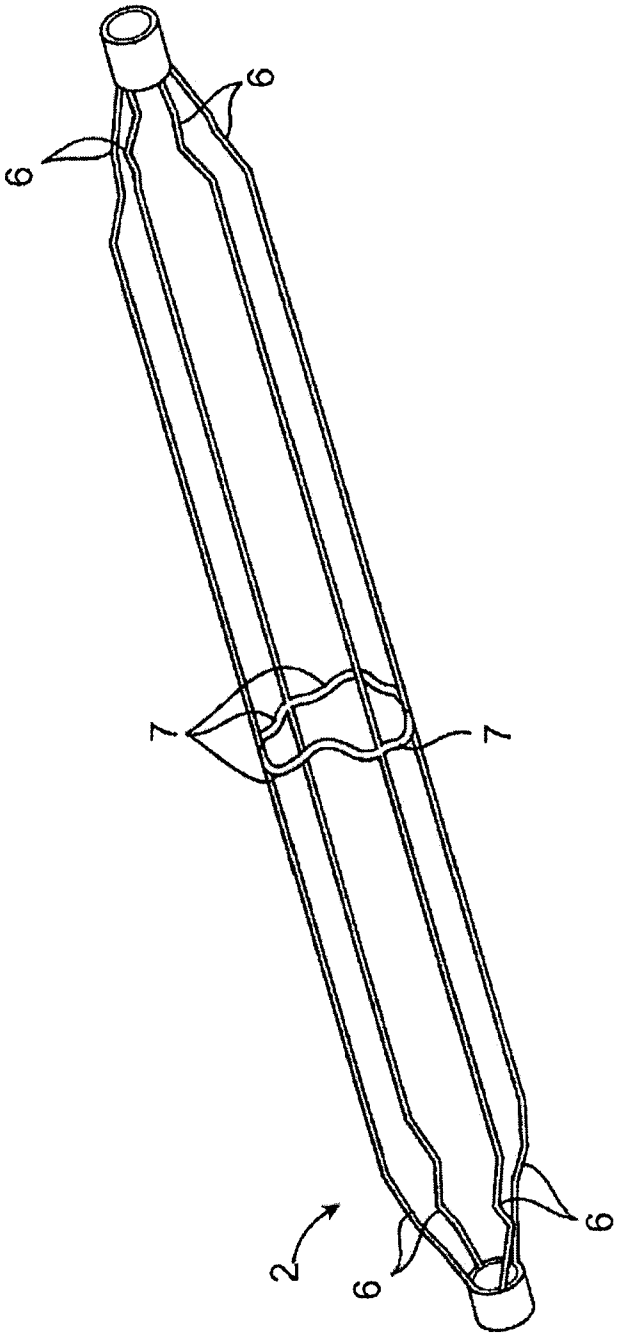

FIG. 3

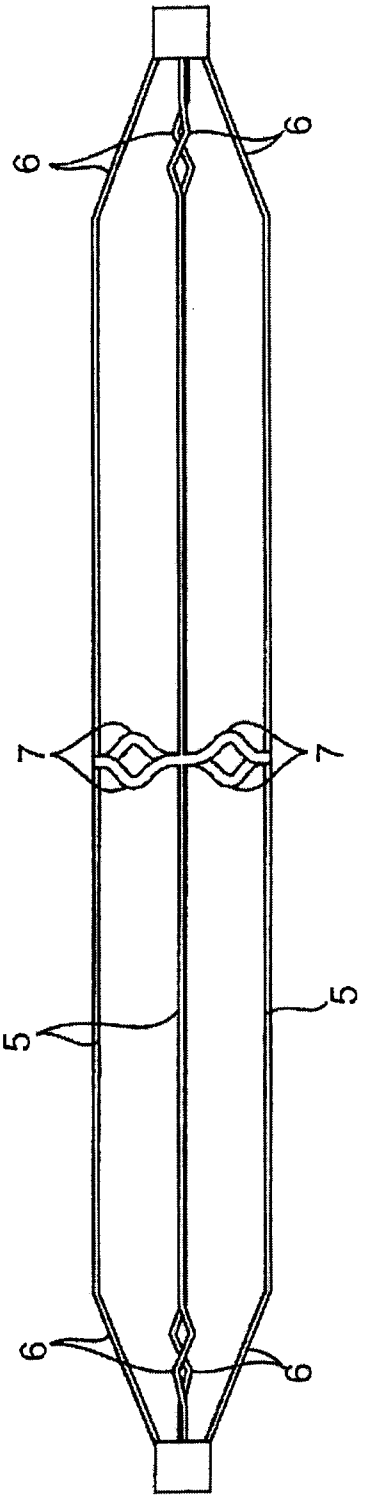

FIG. 4

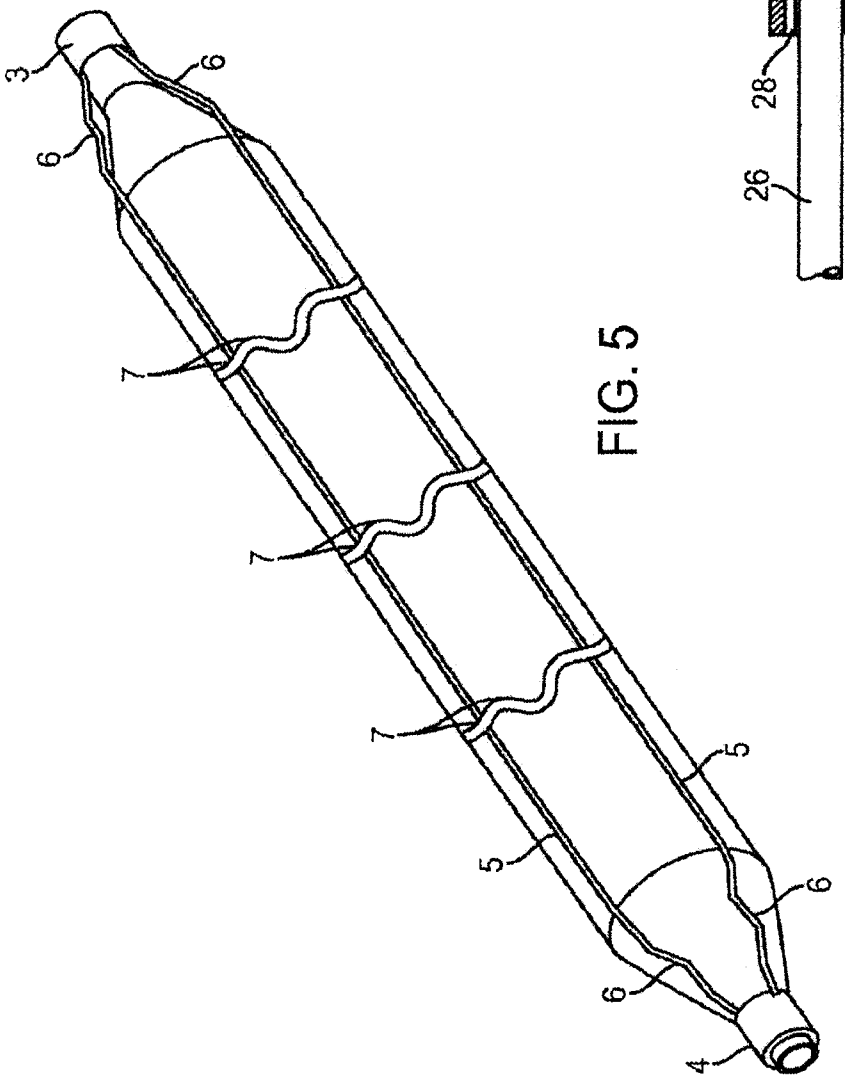

FIG. 5

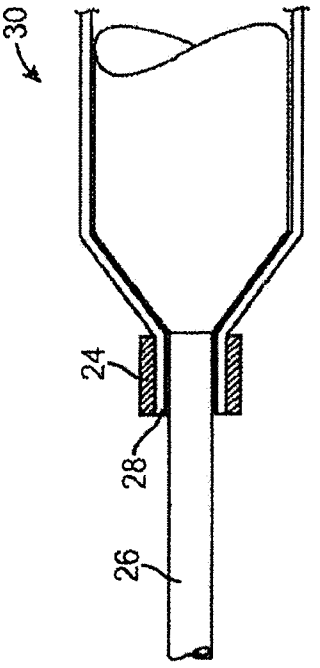

FIG. 5A

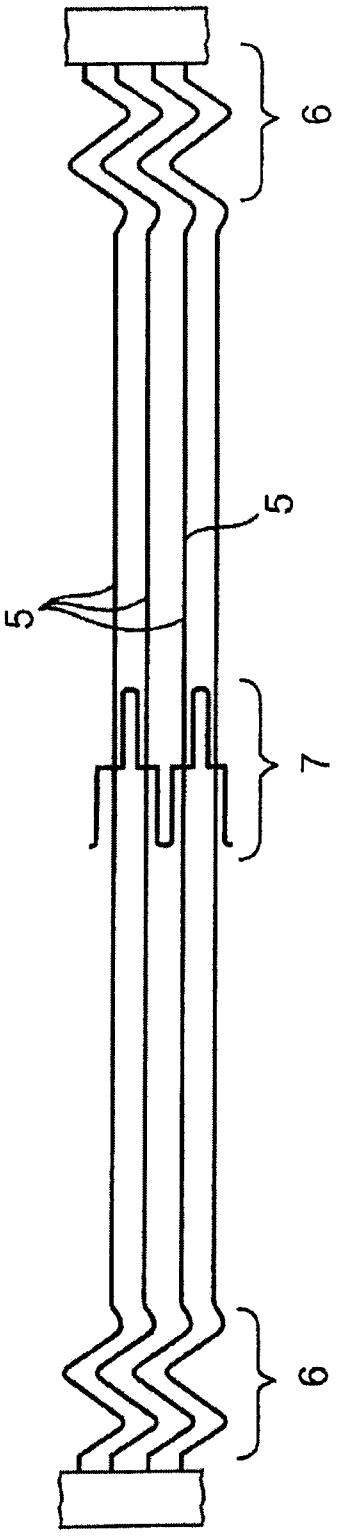

FIG. 6

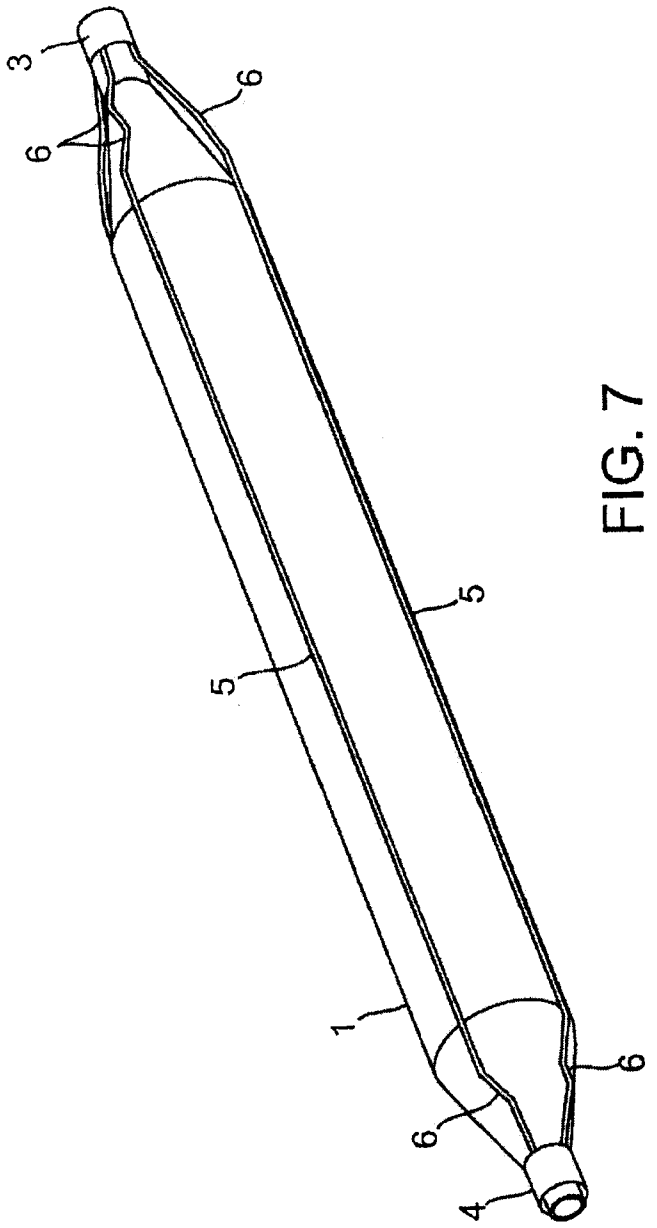

FIG. 7

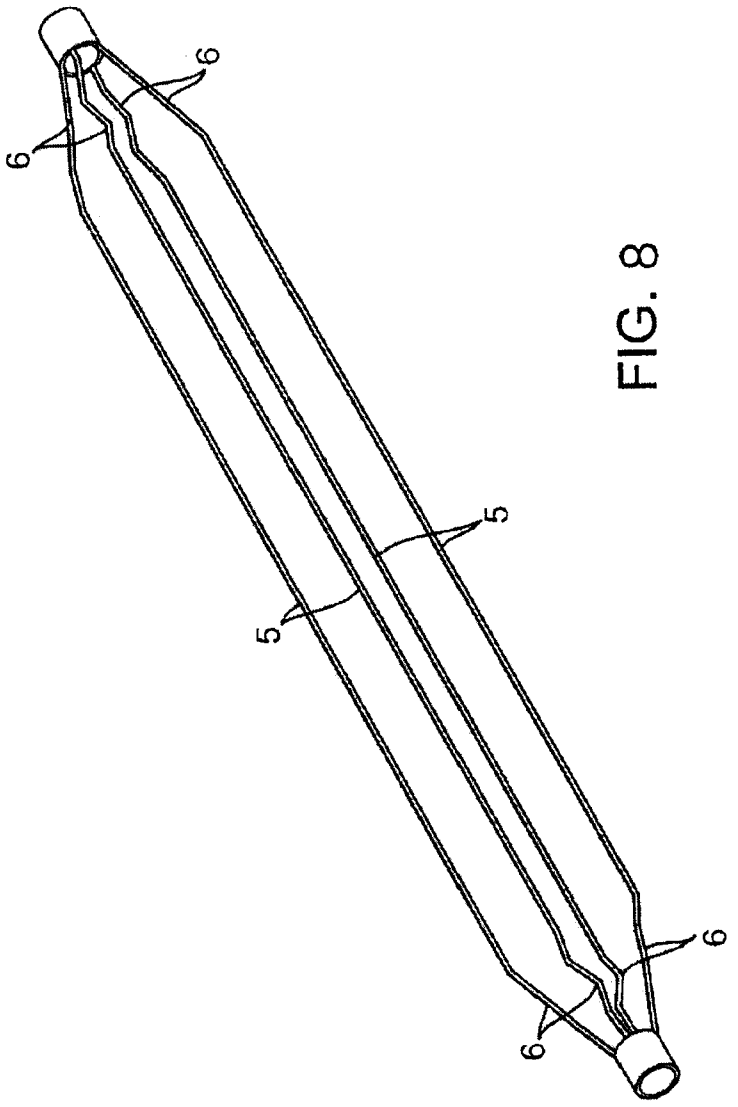

FIG. 8

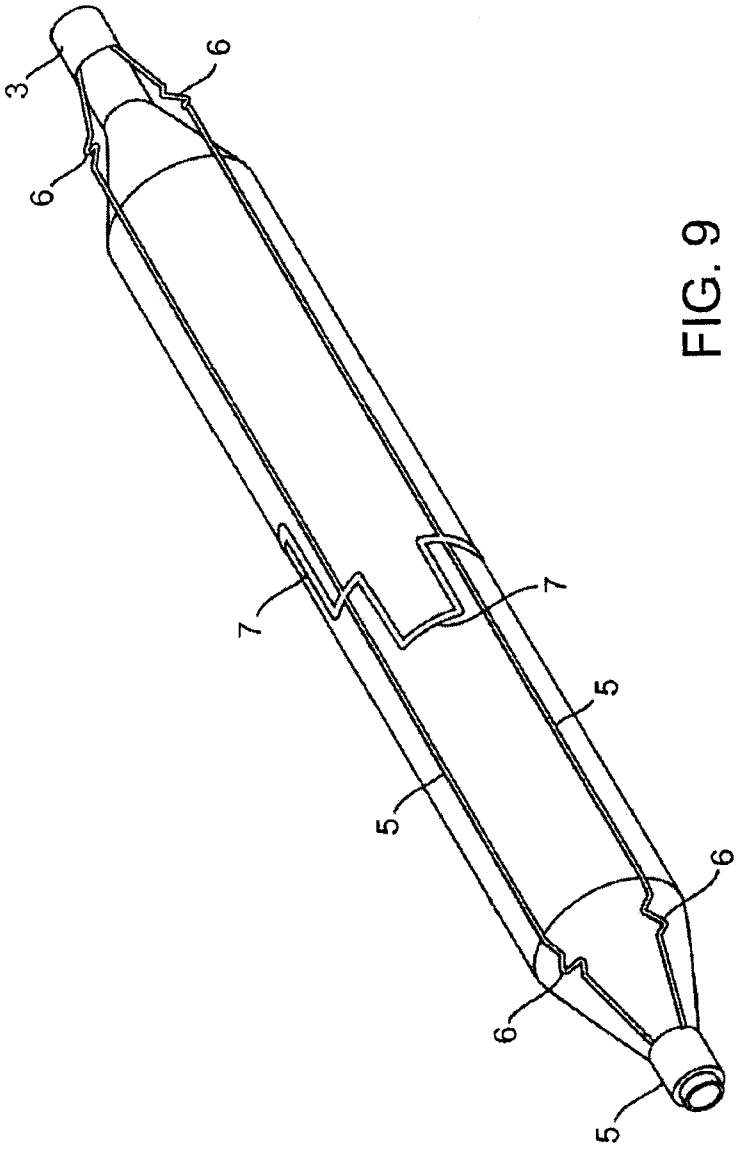

FIG. 9

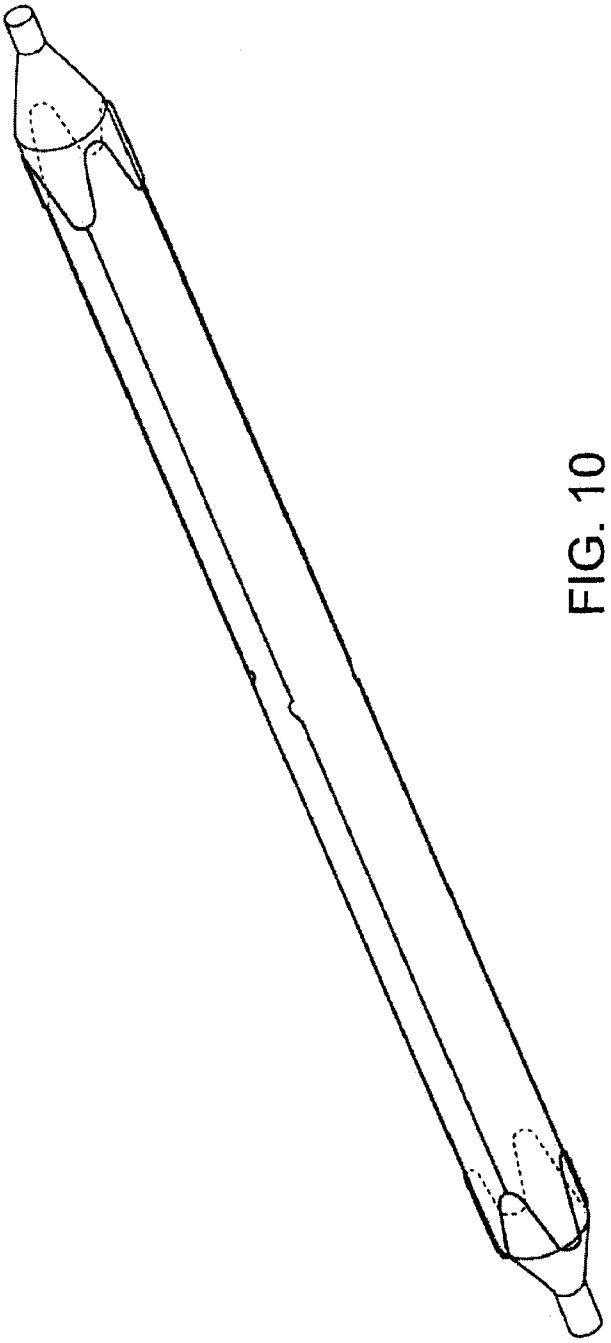

FIG. 10

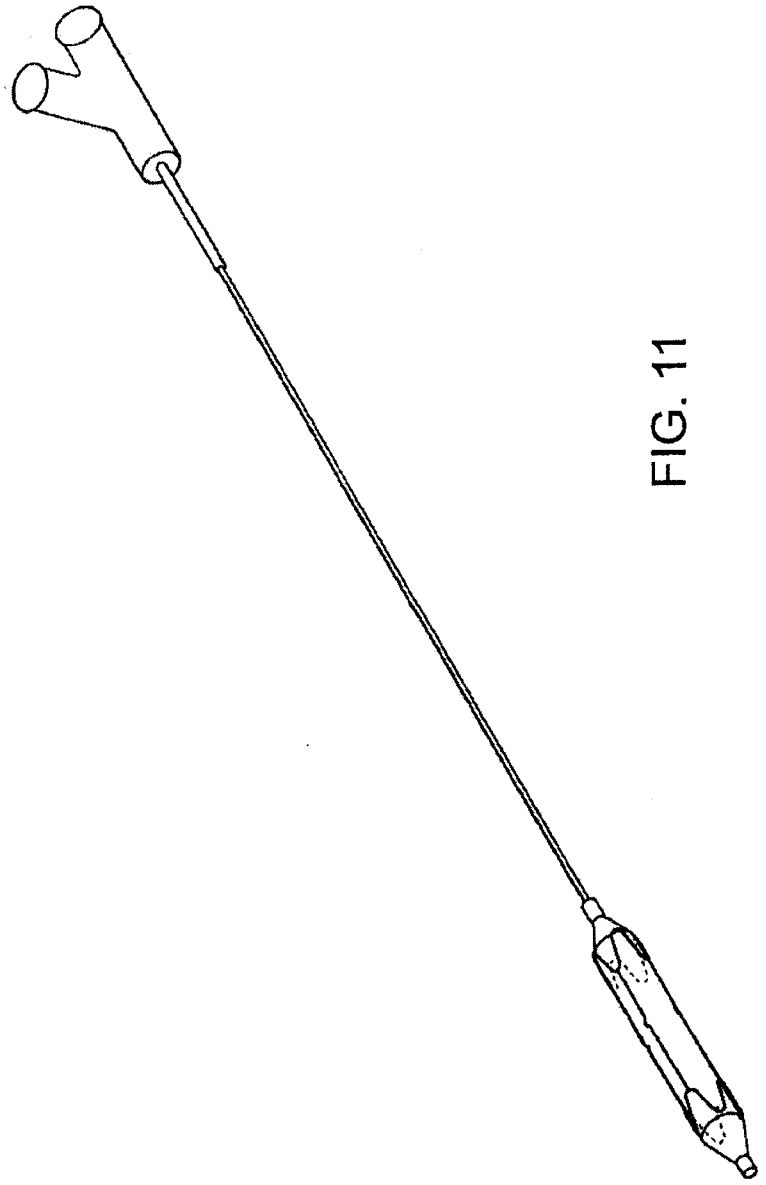

FIG. 11

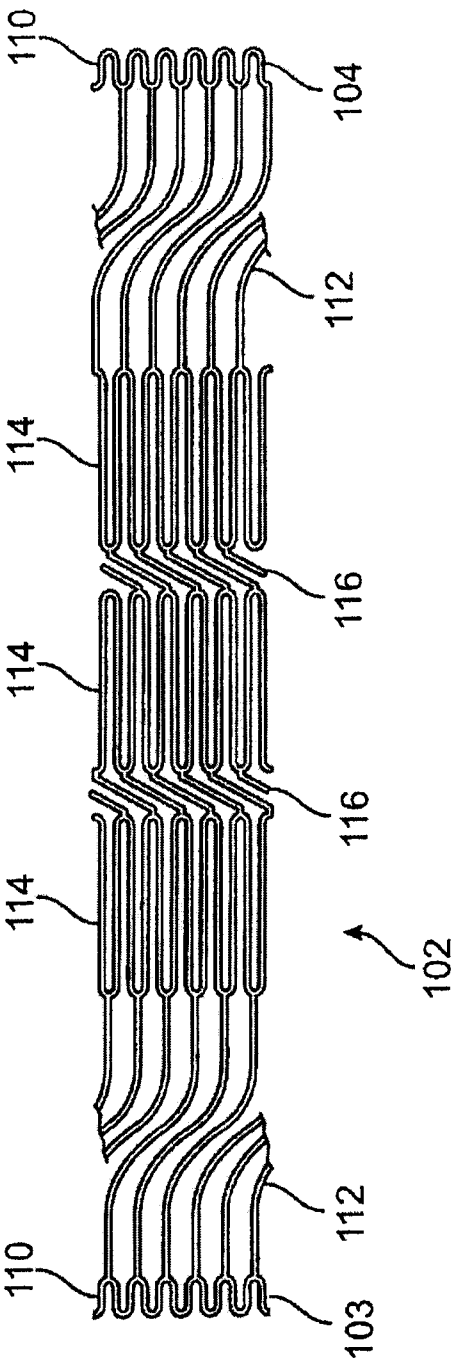

FIG. 12

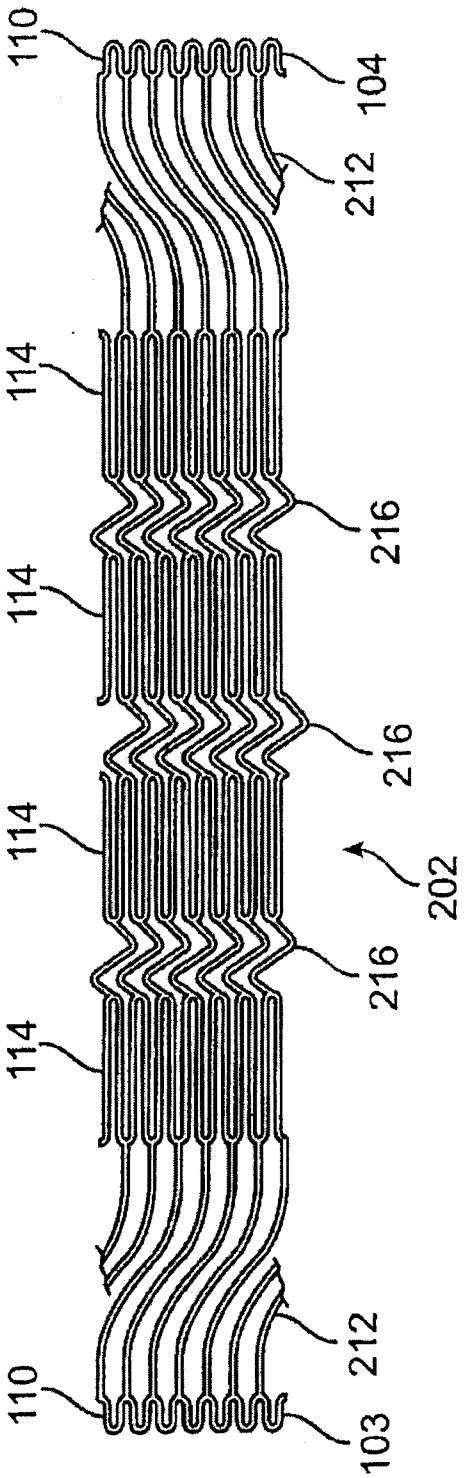

FIG. 13

BALLOON CATHETER WITH NON-DEPLOYABLE STENT

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 10/651,557, filed Aug. 29, 2003, now abandoned which was a continuation-in-part of U.S. patent application Ser. No. 10/399,589, filed on Apr. 18, 2003, now U.S. Pat. No. 7,691,119, which is the U.S. National Stage of PCT Application No. PCT/US02/35547, filed Nov. 6, 2002, which claimed the benefit of U.S. Provisional No. 60/344,982, filed Nov. 9, 2001, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

When a balloon used for percutaneous transluminal angioplasty (PTA) or percutaneous transluminal coronary angioplasty (PTCA) is inflated and forced into contact with the plaque, the balloon can have a tendency to move or slip longitudinally in relation to the lesion or the vessel wall being treated.

Cutting balloons (atherotomy) have recently shown clinical efficacy in preventing the reoccurrence of some types of restenosis (specifically calcified lesions and in-stent restenosis). The cutting balloon is a coronary dilatation catheter with 3 to 4 atherotomes (microsurgical blades) bonded longitudinally on the balloon surface. As the cutting balloon is inflated, the atherotomes move radially and open the occluded artery by incising and compressing the arterial plaque in a controlled manner. An additional advantage of the cutting balloon is that it maintains its position during inflation by using the metal blades on the external surface of the balloon to penetrate into the tissue and prevent the balloon from moving.

Accordingly, it is the principal objective of the present invention to provide a PTA or PTCA balloon that, like a cutting balloon, has a reduced potential of slippage when inflated in a vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an inflated angioplasty balloon incorporating a non-deployable stent according to the present invention.

FIG. **2** is a plan view of the inflated angioplasty balloon and non-deployable stent of FIG. **1**.

FIG. **3** is a perspective view of the non-deployable stent in its expanded condition, as shown in FIG. **1**, with the angioplasty balloon removed so as to more clearly show the stent.

FIG. **4** is a plan view of the non-deployable stent of FIG. **3**.

FIG. **5** is a perspective view of an alternate embodiment of the non-deployable stent associated with an angioplasty balloon that has a longer working length than the angioplasty balloon shown in FIGS. **1** and **2**.

FIG. **5A** is a detailed cross-sectional view of one end of the stent of FIG. **5**.

FIG. **6** is an engineering drawing showing, in plan view, the layout of a non-deployable stent adapted to be used with an angioplasty balloon of 20 mm in length. (All dimensions shown in the drawing are in inches.)

FIG. **7** is a perspective view of an inflated angioplasty balloon incorporating an alternative embodiment of a non-deployable stent which does not include any connecting elements between the struts intermediate the ends of the balloon.

FIG. **8** is a perspective view of the non-deployable stent shown in FIG. **7**, with the angioplasty balloon removed so as to more clearly show the stent.

FIGS. **9** and **10** are perspective views similar to FIGS. **1**, **5**, and **7** showing a further embodiment of the invention.

FIG. **11** is a perspective view of a further embodiment of the present invention showing the balloon and non-deployable stent in conjunction with a catheter.

FIG. **12** is an engineering drawing showing, in plan view, the layout of another embodiment of a non-deployable stent adapted to be used with an angioplasty balloon, in accordance with the present invention.

FIG. **13** an engineering drawing showing, in plan view, the layout of an alternate non-deployable stent of the embodiment of FIG. **12**.

DETAILED DESCRIPTION OF THE INVENTION

The non-deployable stent of the present invention may be used in conjunction with a conventional balloon catheter. A PTA or PTCA catheter (dilatation catheter) may be a coaxial catheter with inner and outer members comprising a guide wire lumen and a balloon inflation lumen, respectively. Each member can have up to 3 layers and can be reinforced with braids. The proximal end of the catheter has a luer hub a guidewire and for connecting an inflation means, and a strain relief tube extends distally a short distance from the luer hub. The distal ends of the outer and inner members may include a taper. The catheter shaft is built using conventional materials and processes. A catheter having multi-durometer tubing with variable stiffness technology is also a possibility. The catheter should be compatible with standard sheaths and guide catheters which are well known in the art. Optionally, the catheter may be a multi-lumen design.

The balloon **1** may be made of either nylon or nylon copolymer (compliant, non-puncture) or PET (high pressure, non-compliant) with a urethane, polymer, or other material and coating known in the art to provide tackiness and/or puncture resistance. The balloon may be a multi-layered balloon with a non-compliant inner layer to a most compliant outer layer or multilayered with similar material. For example, a inner most layer of PET, which provides a higher pressure balloon, surrounded by an outer layer of nylon, which provides a more puncture-resistant surface. The balloon may be from 1.5-12 mm in diameter (1.5-4 mm for coronary and 4-12 mm for peripheral vessels) and 15-60 mm in length (5-40 mm for coronary and up to 60 mm for peripheral vessels). The balloon inflation rated pressure will be from 8-20 atmospheres, depending on the wall thickness of the balloon. When inflated, the balloon ends or necks are cone-shaped.

In keeping with the invention, the balloon is provided with a Nitinol (NiTi) or another material such as for example liquid metal, stainless steel, or other similar material, structure, generally designated **2**, that incorporates bends for both radial and longitudinal expansion of the Nitinol structure **2** in response to longitudinal and radial expansion of the balloon during inflation, so that the Nitinol structure **2** maintains the balloon in its intended position during inflation. This Nitinol structure **2** can be described as a non-deployable or temporary stent that provides for both controlled cracking of vessel occlusion and gripping of vessel wall during an angioplasty procedure. The Nitinol structure **2** comprises a laser cut hypo tube that expands upon inflation of the balloon, but collapses upon deflation of the balloon because of the super-elastic

properties of the Nitinol material, rather than remain expanded in the deployed condition, as would stents in general.

The Nitinol structure or non-deployable stent **2** has a proximal end **3**, a distal end **4**, and, therebetween, anywhere from 3-12 struts or wires **5** (depending on balloon size—but most likely 3-4 struts) with a pattern of radial and longitudinal bends. The use of laser cutting in connection with stent manufacture is well known (See, e.g., Meridan et al. U.S. Pat. No. 5,994,667), as is the use of the super-elastic nickel-titanium alloy Nitinol (see e.g., Huang et al. U.S. Pat. No. 6,312,459).

As seen in FIGS. **1-4**, each end of the four struts **5** has a sinusoidal type bend **6** that allows the laser cut hypo tube to expand longitudinally when the balloon **1** is inflated. The linear length of the sinusoidal type bends **6** is sized to accommodate the longitudinal expansion of the balloon **1** due to inflation. The strut or wire **5** cross sectional shape can be round, triangular, elliptical, oval, or rectangular. Preferred thickness of the struts **5** ranges from 0.003 to 0.010 inch.

At the longitudinal center of the hypo tube, a U-shaped circumferential connector **7** joins each strut **5** to its adjacent strut. As best seen in FIGS. **3** and **4**, the U-shaped connectors **7** are on opposing sides of the central radial axis. The distal end **4** of the hypo tube is adhered to the distal neck of the balloon or the distal end of the catheter shaft, and the proximal end **3** of the hypo tube is either attached to the proximal neck of the balloon or to the proximal end of the catheter shaft. The struts **5** may be attached to the working region of the balloon **1** to assist the hypo tube in staying with the balloon as it inflates and deflates.

Catheter shafts to which the balloon and laser cut hypo tube are attached can have diameters ranging from 2.5 F to 8 F, and the distal end may be tapered and slightly less in diameter than the proximal end.

In FIG. **6**, the dimensions of the laser cut hypo tube are for use with a 3 mm (0.118 in) diameter by 20 mm length balloon. The circumference of a 3 mm balloon is .PI.D=3.14(3 mm)=9.42 mm or 0.37 in. As can be readily appreciated, the total length of all U-shaped connectors **7** (up and back) must be greater than the circumference of the inflated balloon **1**. The length of each U-shaped connector **7** (up and back), may be calculated using the following equation:

$$\frac{\pi d}{n},$$

where d is the diameter of the inflated balloon and n is the number of struts. The total length of the U-shaped bends (up and back) must exceed this length.

The resulting number is divided by 2 to get the length which each up-and-back side of the U-shaped connector should exceed. For example: for a 3 mm balloon compatible, laser-cut hypo tube with four struts, the length of each U-shaped connector (up and back) is 0.37 inch divided by 4=0.0925 in. Further divide by 2 and to get 0.04625 in. This is the length that each side of the U-shaped connector must exceed.

There is also one or more sets of U-shaped connectors **7** in between the sinusoidal bends **6**. The set includes one U-shaped connector for each strut (3 struts—a set of 3 U-shaped connectors; 4 struts—a set of 4 U-shaped connector; and so on). The number of U-shaped connector sets depends on the length of the balloon and thus, the length of the laser cut hypo tube. For a 20 mm length balloon, there is one set of U-shaped connectors spaced 10 mm from the end (at the halfway point along length of balloon). For a 40 mm length balloon, there are three sets of U-shaped connectors spaced in 10 mm increments (the first set is spaced 10 mm from one end; the second set is spaced 10 mm from first set; and the third set is spaced 10 mm from each the second set and the other end). The equation for number of sets of U-shaped connectors.

$$\frac{L-1}{10}$$

where L=length of balloon in mm. Other embodiments, such as those shown in FIGS. **7** and **8**, do not incorporate the intermediate U-shaped connectors.

FIG. **12** is directed to another embodiment of a non-deployable stent **102** which can be used with a conventional balloon catheter, in accordance with the present invention. The stent of this embodiment preferably has a Nitinol structure, though other materials can be used as discussed supra, that incorporates bends for both radial and longitudinal expansion of the stent in response to radial and longitudinal expansion of the balloon during inflation, so that the stent **102** maintains the balloon in its intended position. Similar to the stents of the other embodiments of the present invention discussed supra, the stent comprises a laser cut hypo tube that expands upon inflation of the balloon and collapses upon deflation of the balloon. Further, the stent is preferably secured to the balloon with some type of anchoring means. Preferably, such anchoring means are utilized at the ends of the stent and around the neck of the balloon. Examples of such anchoring means include an adhesive such as for example a UV adhesive, cyanoacrylate, or a two-part epoxy, RF heat welding, solvent bonding, or crimping or swaging the ends of the stent to the shaft. Alternatively, a mechanical anchoring means can be used to anchor the stent to the balloon. With such a means, a small sleeve **24** made of a similar material as the shaft **26** of the catheter is mounted over the ends **28** of the stent **30** and heat welded together where the ends of the stent are sandwiched between the shaft and the sleeve (FIG. **5A**).

FIG. **12** shows the hypo tube of the stent in an unrolled (flat) and non-extended state. The stent **102** has a proximal end **103** and a distal end **104**. At each end, there are cage mounted flanges **110**. These flanges can be used to attach the stent to the neck of the balloon. The flanges also spring open radially to permit insertion of the balloon during assembly. Between the ends, the stent **102** includes extension sections **112**, serpentine rings **114** and elongation links **116**.

Serpentine rings **114** have a serpentine shape and allow the stent **102** to expand radially when a balloon in the stent is inflated. However, as the balloon expands, the serpentine rings **114** will shorten in length. Accordingly, extension sections **112** and elongation links **116** expand longitudinally to compensate for any shortening of the length of serpentine rings **114**. Preferably, elongation links **116** have a z-shape, s-shape or accordion shape, as shown in FIG. **12**.

FIG. **13** is an alternative embodiment showing a stent **202** having the same features as the stent in FIG. **12** except that stent **202** in FIG. **13** has elongated links **216** with a different pattern than the elongated links **116** in stent **102** of FIG. **12**. More specifically, elongated links **216** have a zig zag pattern. Stent **202** of FIG. **13** operates in a substantially similar manner to that of stent **102** in FIG. **12**.

While the present invention is not limited in the number of serpentine rings, extension sections and elongated links used

in the stent, FIG. **13** illustrates a preferred embodiment. The stent **202** in FIG. **13** has from proximal end **103** to distal end **104**, a first extension section **112**, a first set of serpentine rings **114**, a first set of elongated links **216**, a second set of serpentine rings **114**, a second set of elongated links **216**, a third set of serpentine rings **114**, a third set of elongated links **216**, a fourth set of serpentine rings **114**, and a second extension section **112**.

FIG. **13** also shows an example of possible dimensions, in inches, of each of the components of the stent **202**. These dimensions would also be used for each of the similar components in stent **102** in FIG. **12**.

It will be understood that the embodiments and examples of the present invention, which have been described, are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

What is claimed is:

1. A method for performing angioplasty in a blood vessel, said method comprising:

introducing a balloon catheter into a blood vessel, said catheter having a shaft and an inflatable balloon;

inflating the balloon to radially expand a non-deployable stent, wherein a central portion of the stent shortens in length as the stent is radially expanded, wherein the non-deployable stent includes (1) ends which are sandwiched between a sleeve and the shaft of the balloon catheter and (2) a region which expands longitudinally to compensate for foreshortening of the length which results from radial expansion; and

deflating the balloon to allow the non-deployable stent to collapse over the balloon as it deflates.

2. A method as in claim **1**, wherein the non-deployable stent comprises two ends attached to the shaft of the balloon catheter, one end being attached on each side of the balloon.

3. A method as in claim **2**, wherein said region that expands includes at least one extension section between the end and the central section.

4. A method as in claim **3**, wherein said region that expands includes a second extension section between the other end and the central section.

5. A method as in claim **2**, wherein the non-deployable stent includes one or more elongation links along a length of the central section.

6. A method as in claim **1**, wherein the central section of the non-deployable stent comprises a plurality of serpentine rings.

7. An angioplasty catheter comprising:

a catheter shaft having a distal end and proximal end;

an inflatable balloon disposed near the distal end of the catheter shaft;

a non-deployable stent disposed over the inflatable balloon, said stent including a central section which radially expands and axially foreshortens when the balloon is inflated, an end, and an extension section between the end and the central section;

wherein the end of the stent is sandwiched between a sleeve and the shaft on at least one side of the balloon and wherein the extension section of the stent longitudinally expands to accommodate axial shortening of the central section of the stent upon radial expansion of the stent resulting from balloon expansion.

8. An angioplasty catheter as in claim **7**, wherein the stent includes a second end which is sandwiched between a sleeve and the catheter shaft on another side of the balloon.

9. An angioplasty catheter as in claim **8**, the stent further comprises a second extension section between the second end and the central section of the stent.

10. An angioplasty catheter as in claim **9**, wherein the central section comprises a plurality of axially joined serpentine rings.

11. An angioplasty catheter as in claim **8**, further comprising at least one elongation link between adjacent serpentine rings in the central section of the stent.

12. An angioplasty catheter as in claim **11**, including a plurality of elongation links between adjacent serpentine rings in the central section of the stent.

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